Maidstone and Tunbridge Wells NHS Trust

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Freedom of Information Act 2000

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to policies and procedures.

I am writing to you to request the provision of several documents from the Trust approved document management database which relate to the main policies and procedures in place.

If at all possible, please could you provide the following documents (unique ID in brackets):

1. Critical Medicines where Timeliness of Administration is Crucial (RWF-OWP-APP299);
2. Critical Medicines Loading Doses (RWF-OWP-APP300);
3. Standard Operating Procedure for Prescribing, Preparing and Administering Injectable Medicines in Clinical Areas (RWF-OPPM-CSS2);
4. Standard Operating Procedures for the Management of Controlled Drugs in Operating Theatres (RWF-OPG-CSS4);
5. Standard Operating Procedures for the Management of Controlled Drugs in Wards and Departments (RWF-OPG-CSS5); AND
6. All of the above policies as in place on February and March 2014, if different from the above.

The requested policies and procedures are attached to the end of this letter.

Archived policies and procedures:

Critical Medicines Where Timeliness of Administration is Crucial

It is important to recognise that harm can arise from the omission or delay of the administration of a medicine and, if that medicine is critical (e.g. insulin, antibiotics, anticoagulants) the consequences can be serious or even fatal.

The Trust expects that all staff should endeavour to prescribe and administer all medicines in a timely manner.

The NPSA Alert 2010/RRR009 highlighted the risks to patient safety of omitted or delayed doses. As part of the recommendations from this document a list of 'critical' medicines where timeliness of administration is crucial was recommended. This list is available in the Medicines Management section on Datix Guidelines for information.

Due to the risk of patient harm, prescription, dispensing and administration of the following drugs must never be unintentionally omitted or delayed.

Omission or delay of these drugs constitutes an adverse incident and is reportable to the NPSA.

Definitions

Omission = Failure to prescribe a drug in a timely manner
Failure to administer a dose before the next dose is due or, in the case of once only doses, failure to administer a drug within 2 hours of the time the dose is due

Delay = Administration of a drug 2 hours or more after the time the dose is due (may be less for some drugs or indications – see list)

Drug Name or Class	Rationale for Inclusion
Systemic antimicrobials (including antibiotics, antifungals, antivirals and antimalarials) within the first 48 hours of therapy	Potential worsening of systemic infection and deterioration of condition
Gentamicin in neonates must be given within 1 hour of the time the dose is due	Requirement of NPSA/2010/PSA001 Safer Use of intravenous gentamicin for neonates
Antiretrovirals	Potential for emergence of viral resistance
Insulin	Poor glycaemic control and potential for symptomatic hyperglycaemia
Oral hypoglycaemic agents	Poor glycaemic control and potential for symptomatic hyperglycaemia
Glucose/glucagon	Failure to treat symptomatic hypoglycaemia (medical emergency) with risk of patient harm
Opiates prescribed regularly for the management of severe chronic pain. Includes regular oral therapy, parenteral therapy and transdermal therapy	Loss of pain control. Increased need for intermittent analgesic doses
Naloxone	Failure to treat opiate toxicity (medical emergency) with risk of patient harm

Immunosuppressants for transplant patients	Risk of transplant rejection due to sub therapeutic levels
Chemotherapy, including cytotoxics and adjunctive therapies prescribed as part of an approved chemotherapy regimen	Delay in treatment and disruption of chemotherapy regimen scheduling. Treatment failure
Corticosteroids	Treatment failure in acute conditions. Risk of Addisonian crisis in steroid dependency
Anticoagulants (therapeutic)	Progression of thrombus and risk of serious embolic episode (stroke/PE)
Anticoagulants (thromboprophylaxis)	Risk of thrombus and serious embolic episode
Parenteral electrolyte replacement (including potassium, calcium, magnesium, phosphate) for the urgent treatment of symptomatic deficiencies	Deterioration in clinical condition
Calcium resonium, glucose/insulin	Emergency treatment of symptomatic hyperkalaemia
Parenteral **bisphosphonates** in the treatment of severe symptomatic hypercalcaemia	
Glucose infusions in normoglycaemic patients receiving intravenous insulin infusions	Risk of hypoglycaemia
Drugs administered as **prophylactic agents** to reduce toxicity of other drugs e.g. phenytoin/busulphan, chlorphenamine and hydrocortisone/Campath, acetylcysteine/contrast media	Increased risk of adverse drug events with known toxic medicines
Antiepileptic agents	Loss of seizure control
Anti-Parkinsonian agents	Loss of symptom control. 'Get it on time' campaign
Nebulised **bronchodilator** therapy	Deterioration in clinical condition
Resuscitation drugs and reversal agents including **plasma expanders**	Failure to treat medical emergencies with risk of patient harm
Antiplatelets and thrombolytics	Increased risk of poor outcomes following MI Risk of re-stenosis in patients undergoing PCI
Beta-blockers perioperatively	May cause tachyarrhythmias
Analgesics for the management of post-operative pain	Patient experiences avoidable pain
Benzodiazepines and parenteral vitamins for the management of acute alcohol withdrawal syndromes	
Oxygen	Increased risk of harm from prolonged hypoxia

References

NPSA Rapid Response Alert (NPSA/2010/RRR009) 'Reducing Harm from Omitted and Delayed Medicines in Hospital'
King's College Hospital Omitted Medicines List

Critical Medicines With Loading Doses Likely to Cause Harm

A loading dose is an initial large dose of a medicine used to ensure a quick therapeutic response. It is usually given for a short period before therapy continues with a lower maintenance dose. The use of loading doses of medicines can be complex and error prone. Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death.

The trust expects that all staff should endeavour to prescribe and administer loading and maintenance doses safely and correctly.

The NPSA Alert 2010/RRR018 highlighted the risks to patient safety of incorrect loading doses, omitted or delayed administration of loading doses, or unintentional continuation of loading doses. As part of the recommendations a risk assessment was carried out to identify a list of critical medicines where accurate loading dose prescribing and administration is crucial. This list is available in the Medicines Management section on Datix Guidelines for information.

Due to the risk of patient harm these must be effective communication regarding loading dose and subsequent maintenance dose regimens when prescribing, dispensing and administering critical medicines. And clinical checks should be performed by medical, nursing and pharmacy staff (when available) to ensure loading and maintenance doses are correct.

Critical Medicines

- Amiodarone
- Aminophylline
- Phenytoin
- Warfarin
- Digoxin
    - Heparin
    - Potassium
    - Alteplase
    - Danaparoid
    - Infliximab
    - Lidocaine
    - Teicoplanin
    - Tirofiban

See below for more information about each of the critical drugs identified.

PRESCRIBING INFORMATION FOR THE ADMINISTRATION OF AMIODARONE IN ADULT PATIENTS

1. **Loading Dose** (when required)

   A loading dose of 300mg shoule be given as an IV Infusion of:

   - 300mg Amiodarone in 100ml Glocose 5% over 30 minutes

   For **Emergency Control ONLY** a slow IV bolus may be used.

2. **Maintenance Infusion**

   - Amiodarone 900mg in 500mL Glucose over 24 hours (21mL/hr)

   This may be continued as necessary according to response and clinical condition.

3. **Administration Guidance**

   Administer centrally e.g. via long line (to avoid thrombophlebitis).

   Amiodarone is an irritant to veins. The vascular access site should be regularly checked for any signs of irritation (redness, pain and swelling). The vascular access should be re-sited should any irritation occur.

4. **Interactions**

   Amiodarone can interact with many drugs. All concurrent medications should be assessed for potential interactions when amiodarone is started. Some clinically important interactions include:

   - ***Warfarin*** – the anticoagulant effect of warfarin will be increased in most people treated with amiodarone. Maximal effect occurs between two and seven weeks after starting treatment with amiodarone. Monitor INR closely during this period.
   - ***Digoxin*** – digoxin levels can be approximately doubled. Monitor digoxin levels and consider halving the digoxin dose.
   - ***Simvastatin*** – doses above 20mg should not be used with amiodarone because of increased risk of myopathy.
   - ***Phenytoin*** – phenytoin levels can be markedly raised in patients taking amiodarone. Monitor phenytoin levels closely and reduce dose as necessary.

5. **Converting from IV to Oral**

   If the decision is taken to continue amiodarone long term the following regimen should be followed.

   Continue the infusion for 12 hours after the first oral dose

   - 200-400mg THREE times a day for 7 days then
   - 200-400mg TWICE a day for 7 days
   - 200-400mg ONCE a day thereafter

6. **Monitoring**

   Monitor liver and thyroid function for patients on long term therapy. The patient should have a baseline and 6 monthly LFT and TFT. Patients should also have a baseline chest x-ray which should be repeated if the patient experiences unexplained dyspnoea or non-productive cough as amiodarone can cause pneumonitis, fibrosis and pleuritis.

PRESCRIBING INFORMATION FOR THE ADMINISTRATION OF AMINOPHYLLINE

1. **Patients already taking oral theophylline or aminophylline**

   A loading dose must **NOT** be given.

2. **Patients NOT already taking oral theophylline or aminophylline**

   A loading dose should be given

   The patient's weight should be known before the drug is prescribed [in an emergency an estimate can be accepted until patient can tell you their weight or be weighed]

   Loading dose = 5mg/kg *(as an IV infusion in 100ml sodium chloride 0.9% or glucose 5% over 20 minutes). Maximum infusion rate = 25mg / minute*

3. **Maintenance Infusion**

   Aminophylline 1g in 1L of sodium chloride 0.9% (preferred choice) or glucose 5%.

   The initial rate of infusion (mL/hour) can be calculated using the table overleaf.

4. **Drug Interactions**

   Theophylline is metabolised by the liver. Therefore drugs that inhibit or induce hepatic enzymes will affect theophylline clearance.

   CIPROFLOXACIN, ERYTHOMYCIN AND CLARITHROMYCIN decrease theophylline clearance and can therefore lead to toxicity - *the rate of aminophylline infusion should be* ***HALVED***

   There are many other drugs that interact with theophylline – *Please refer to the BNF.*

5. **Measuring Theophylline and Potassium Levels**

   The therapeutic range for theophylline is: 10 – 20 mg/L

   Theophylline *(not aminophylline)* is measured, as this is the active constituent of the drug.

   When should the level be checked first?

   If a loading dose has been given: **6 hours** after starting the infusion.

   If toxicity is a risk: **6 hours** after starting the infusion.

   All other patients: **12-18 hours** after starting the infusion.

   Repeat levels **MUST** be taken **every 24 hours.**

   Infusion rates may be adjusted using the equation:

   $$\textit{New Infusion Rate} = \frac{\textit{15 x Current Infusion Rate}}{\textit{Current Theophylline Level (mg/L)}}$$

   The patient's potassium levels should be checked within 12 hrs of starting an infusion (and as necessary thereafter)

6. **Converting from IV to Oral**

   - When converting from aminophylline to theophylline, a conversion factor is necessary. Aminophylline contains 80% theophylline, therefore the conversion factor = 0.8.
   - When converting to oral aminophylline, there is no need for a conversion factor.
   - Give the first oral dose as the rate of aminophylline infusion is reduced to zero over 8-12 hours.
   - A 6 – 8 hour post-dose level **MUST** be taken after 2 days.

Example	
60kg patient, rate of infusion	= 30ml/hour
Total daily dose	= 720mg of aminophylline (of which 80% is theophylline)
Therefore dose of theophylline	= 720mg x 0.8 = 576mg
Give the nearest practical dose	= Uniphyline Continuous® 300mg bd

Consult the formulary of *BNF* for aminophyllne / theophylline preparations available.

Dosing Information for Intravenous Phenytoin in Status Epilepticus in Adults

Preparation: Vials contain 250mg phenytoin in 5ml

Single Loading dose: **20mg/kg** *(from BNF 62)*

LOADING DOSE

Clinician to decide whether actual or ideal body weight should be used

Weight (kg)	Loading dose (mg)	Volume of Phenytoin (mL)	Volume of Sodium Chloride 0.9% (mL)	Infusion time (minutes)
36-41	800	16	100	30-60
42-46	900	18	100	30-60
47-52	1000	20	100	30-60
53-57	1100	22	250	60
58-63	1200	24	250	60
64-69	1300	26	250	60
70-74	1400	28	250	60
75-80	1500	30	250	60
81-85	1600	32	250	60
86-91	1700	34	250	60
92-96	1800	36	250	60
97 upwards	1900	38	250	60

How do I administer an infusion of phenytoin?	Add the phenytoin to the volume of sodium chloride 0.9% in the table. Infusions containing greater than 10mg/ml Phenytoin are likely to precipitate during use and should be avoided. **Infusion time -** See table. The max rate of administration in an adult is 50mg per minute. Because of the risk of precipitation always use an infusion line incorporating a 15 micron filter.
Who supplies these infusion lines?	15 micron filter lines suitable for a Graseby 500 pump can be obtained from pharmacy. Clinical areas that shock phenytoin should consider keeping a small supply of these lines.

MAINTENANCE DOSE

Maintenance dose:

Initially: 100mg every 6-8hours (usually start with 100mg three times a day)

Dose may be lower in patients with low albumin levels or in patients receiving other medicines which interact with phenytoin. Contact your pharmacist for advice about interactions between medications.

How do I administer a maintenance dose of phenytoin?	Best practice is to administer a bolus dose of 100mg over 3 – 5 minutes, but dose can be administered as an infusion. **Once a phenytoin level has been recorded:** Dose should be adjusted according to the serum phenytoin level. See below for advice on timing of samples and monitoring.

Continued overleaf

Therapeutic drug monitoring: Target phenytoin level is 10-20 mg/L*
*(* Level is different in patients prescribed sodium valproate – 5-10mg/L)*

When do I take levels?	**After loading dose:** Phenytoin levels should eb taken **between 6 - 24 hours** after loading dose has been given. This level will guide to assess whether therapeutic range has been achieved.
	After maintenance dose: This depends on the clinical situation. If a patient is poorly controlled or there are concerns about absorption levels should be taken once of twice a week (or more often). For non-acute cases, particularly those managed as out-patients, levels should be taken **2 – 3 weeks** after treatment initiated or if the dose has not been changed. A trough level is required before the morning dose. Levels may also be need to be taken more frequently in malnourished patients, patients with liver impairment or patients taking medicines which interact with phenytoin. The pharmacokinetics of phenytoin mean that a small dose increase can produce a large increase in phenytoin levels. If a dose increase is required dosages should be changed in small increments only to avoid toxicity. Contact a pharmacist or neurologist for advice regarding adjusting phenytoin doses.

Other monitoring:

Parameters:	BP, ECG, O_2 saturation and respiratory rate
Signs of phenytoin toxicity	The initial symptoms are ataxia, lethargy, slurred speech, nausea and vomiting. The patient may become comatose.

Converting to oral phenytoin

Convert to oral preparation when patient is able to tolerate oral feeds. Give total daily dose as a single dose. Formulations of phenytoin are not bio-equivalent.	
Converting from Intravenous dose to oral dose when patient can swallow capsules	Total daily intravenous dose is equal to total daily oral dose
Converting from Intravenous dose to oral dose when patient requires suspension	If daily intravenous dose is 300mg then daily oral liquid dose is 270mg Phenytoin suspension interacts with enteral feeds causing decreased absorption. Phenytoin should **NEVER** be administered via enteral feeding tube. Continue intravenous injection

Warfarin

Please refer to trust formulary for the Medicines Information Frequently asked Questions section on Anticoagulants for guidance on warfarin loading and prescribing.

Digoxin

Please refer to trust formulary for the section on cardiac glycosides and therapeutic drug monitoring for digoxin loading and prescribing guidance.

Drug	**Digoxin**
Signs of toxicity	Nausea & vomiting Diarrhoea Visual disturbances Confusion Delirium
To calculate dose:	**14 microgram/kg oral loading** **10 microgram/kg IV loading** **Maintenance – 125 microgram or less with reduced renal function or low body weight**
What alters dosage:	Renal function Weight Amiodarone (reduce dose by half)
Obesity - how to change dosage:	Calculate on Ideal Body Weight
Target range for drug levels	0.5-1.0 microgram/l
Take levels on:	7 days
When to sample:	6-11 hrs post-dose

Heparin

Please refer to trust formulary for the Medicines Information Frequently asked Questions section on Anticoagulants for guidance on heparin loading and prescribing.

Potassium

Please refer to trust formulary for the therapeutic section on Fluid and Electrolytes for guidance on potassium prescribing.

Alteplase

Please refer to trust formulary for the Therapeutic section on Fibrinolytics and the prescribing guidelines section for “Guidelines for effective management of TIA and Stroke” to find information about alteplase prescribing.

Danaparoid

Please refer to trust formulary for the Medicines Information Frequently asked Questions section on anticoagulation for guidance on danaparoid prescribing.

Infliximab

Please refer to trust formulary for the Therapeutic section on Chronic Bowel Disorders, Drugs Used in Rheumatic Disease & Gout and preparations for Eczema & Psoriasis for information about infliximab prescribing.

Lidocaine

Please refer to trust formulary for the Therapeutic section on Anti-arrhythmic drugs and local anaesthesia for guidelines about lidocaine prescribing.

Teicoplanin

Please refer to trust formulary for the Therapeutic section on Other Antibacterials for guidelines about teicoplanin prescribing.

Tirofiban

Please refer to trust formulary for the Therapeutic section on Antiplatelet Drugs for guidelines about tirofiban prescribing.

Standard Operating Procedure for Prescribing, Preparing and Administering Injectable Medicines in Clinical Areas

Please note that these procedures EXCLUDE the prescription, supply and administration of INTRATHECAL chemotherapy which is subject to a separate policy

Introduction

The use of injectable medication has many healthcare benefits for patients. The complexities associated with the prescription, preparation and administration of injectable medicines means that there are greater potential risks for patients than for other routes of administration. Weak operating systems increase the potential risk of harm, and safe systems of work are needed to minimise these risks.

These procedures refer to all injectable medicines routes (except intrathecal), however more specialist routes e.g. sub-conjunctival etc. may be subject to additional and more specific guidance.

This Trust Standard Operating Procedure for Prescribing, Preparing and Administering Injectable Medicines in Clinical Areas forms part of the Trust Medicines Policy and should be read in conjunction with Chapter 6 of that Policy.

This document has been written incorporating guidance from the NPSA 'Promoting Safer Use of Injectable Medicines' documents.

1: Prescribing

1.1 All prescriptions for injectable medicines, where relevant (and including those items prepared aseptically within the Pharmacy Departments), must specify the following:

- the approved medicine name;
- the dose and frequency of administration;
- the date and route of administration;
- the date on which treatment should be reviewed;
- the prescriber's signature;

1.2. Where relevant, the prescription, or a readily available local protocol, must also specify the following:

- brand name and formulation of the medicine;
- concentration or total quantity of medicine in the final infusion container or syringe;
- name and volume of diluent and/or infusion fluid;
- rate *and* duration of administration;
- stability information to determine the expiry date of the final product;
- the age and weight of any patient under 16 years of age, where relevant;
- arrangements for fluid balance or clinical monitoring should be made on an individual patient basis and according to local protocol and clinical need.

2: Preparation

2.1 General

2.1.1 Trust staff must not prepare substances for injection in advance of their immediate use or administer medication drawn into a syringe or container by another practitioner when not in their presence.

2.1.2 Read all prescription details carefully and confirm that they relate to the patient to be treated.

2.1.3 Calculate the volume of medicine solution needed to give the prescribed dose. Write the calculation down and obtain an independent check by another qualified healthcare professional.

2.1.4 Ensure that the area in which the medicine is to be prepared is as clean, uncluttered and free from interruption and distraction as possible. Preparation must take place in an area dedicated to this process e.g. clinical room.

2.1.5 Assemble all materials and equipment: sharps bin for waste disposal, medicine ampoule(s)/vial(s), diluent, syringe(s), safety needle(s), alcohol/disinfectant wipes, disposable protective gloves, clean re-usable plastic tray.

Check the following:

- expiry dates;
- damage to containers, vials or packaging;
- that medicines were stored as recommended, e.g. in the refrigerator.

2.1.6 Beware of the risk of confusion between similar looking medicine packs, names and strengths. Read all labels carefully.

2.1.7 Check that:

- the formulation, dose, diluent, infusion fluid and rate of administration correspond to the prescription and product information;
- the patient has no known allergy to the medicine;
- you understand the method of preparation.

2.1.8 Prepare the label for the prepared medicine (see 2.7 below).

2.1.9 Clean your hands according to local policy.

2.1.10 Put on a pair of disposable protective gloves.

2.1.11 Use a disinfectant wipe or spray (as recommended by current Infection Control Policy) to disinfect the surface of the plastic tray or use a disposable tray.

2.1.12 Assemble the required syringe(s) and safety needle(s). Peel open wrappers carefully and arrange all ampoules/vials, syringes and needles neatly in the tray.

2.1.13 Use a 'non-touch' technique, i.e. avoid touching areas where bacterial contamination may be introduced, e.g. syringe-tips, needles, vial tops. Never put down a syringe attached to an unsheathed needle.

2.1.14 Prepare the injection by following the manufacturer's product information or local guidelines, and the relevant guidance in 2.2 to 2.7 below.

2.2 Withdrawing solution from an ampoule (glass or plastic) into a syringe

2.2.1 Tap the ampoule gently to dislodge any medicine in the neck.

2.2.2 Snap open the neck of glass ampoules (away from the operator), using an ampoule snapper if required.

2.2.3 Attach a filter needle to a syringe (for glass ampoules) and draw the required volume of solution into the syringe. Plastic ampoules do not require a needle to be fitted to the syringe. Tilt the ampoule if necessary.

2.2.4 Invert the syringe and tap lightly to aggregate the air bubbles at the needle end. Expel the air carefully.

2.2.5 Remove the needle from the syringe and fit a new needle or insert the syringe into syringe packaging.

2.2.6 Label the syringe (see 2.7 below).

2.2.7 Keep the ampoule and any unused medicine until administration to the patient is complete to enable any further checking procedures to be undertaken.

2.2.8 If the ampoule contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.

2.2.9 The neck of some plastic ampoules is designed to connect directly to a syringe without use of a needle, after the top of the ampoule has been twisted off.

2.3 Withdrawing a solution or suspension from a vial into a syringe

2.3.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol/disinfectant wipe e.g. Sanicloth CHG 2%. Allow to dry for at least 30 seconds.

2.3.2 With the safety needle, draw into the syringe a volume of air equivalent to the required volume of solution to be drawn up.

2.3.3 Insert the safety needle into the vial through the rubber septum.

2.3.4 Invert the vial. Keep the needle in the solution and slowly depress the plunger to push air into the vial.

2.3.5 Release the plunger so that solution flows back into the syringe.

2.3.6 If a large volume of solution is to be withdrawn, use a push-pull technique. Repeatedly inject small volumes of air and draw up an equal volume of solution until the required total is reached. This ‘equilibrium method’ helps to minimise the build-up of pressure in the vial.

2.3.7 Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.

2.3.8 With the vial still attached, invert the syringe. With the needle and vial uppermost, tap the syringe lightly to aggregate the air bubbles at the needle end. Push the air back into the vial.

2.3.9 Fill the syringe with the required volume of solution then draw in a small volume of air. Withdraw the needle from the vial.

2.3.10 Expel excess air from the syringe. Remove the needle, dispose of in a sharps bin and insert the syringe into the syringe packaging.

2.3.11 The vial(s) and any unused medicine should be kept until administration to the patient is complete.

2.3.12 If the vial contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.

2.4 Reconstituting powder in a vial and drawing the resulting solution or suspension into a syringe

2.4.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.

2.4.2 Use the procedure in 2.2 above to withdraw the required volume of diluent (e.g. water for injections or sodium chloride 0.9%) from ampoule(s) into the syringe.

2.4.3 Inject the diluent into the vial. Keeping the tip of the needle above the level of the solution in the vial, release the plunger. The syringe will fill with the air which has been displaced by the solution (if the contents of the vial were

packed under a vacuum, solution will be drawn into the vial and no air will be displaced). If a large volume of diluent is to be added, use a push-pull technique (see 2.3.6).

2.4.4 With the syringe and safety needle still in place, gently swirl the vial(s) to dissolve all the powder, unless otherwise indicated by the product information. This may take several minutes.

2.4.5 Follow the relevant steps in 2.3 above to withdraw the required volume of solution from the vial into the syringe.

2.4.6 Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.

2.4.7 If a purpose-designed reconstitution device is used, the manufacturer's instructions should be read carefully and followed closely.

2.5 Adding a medicine to an infusion

2.5.1 Prepare the medicine in a syringe using one of the methods described in 2.2 to 2.4 above.

2.5.2 Check the outer wrapper of the infusion container is undamaged.

2.5.3 Remove the wrapper and check the infusion container itself in good light. It should be intact and free of cracks, punctures/leaks.

2.5.4 Check the infusion solution, which should be free of haziness, particles and

discolouration.

2.5.5 Where necessary, remove the tamper-evident seal on the additive port according to the manufacturer's instructions or wipe the rubber septum on the infusion container with an alcohol/disinfectant wipe e.g. Sanicloth CHG 2% and allow to dry for at least 30 seconds.

2.5.6 If the volume of medicine solution to be added is more than 10% of the initial contents of the infusion container (more than 50ml to a 500ml or 100ml to a 1litre infusion), an equivalent volume must first be removed with a syringe and needle.

2.5.7 Inject the medicine into the infusion container through the centre of the injection port, taking care to keep the tip of the needle away from the side of the infusion container. Withdraw the needle and invert the container at least five times to ensure thorough mixing before starting the infusion.

2.5.8 Do not add anything to any infusion container other than a burette when it is hanging on the infusion stand since this makes adequate mixing impossible.

2.5.9 Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before administration is re-started, the contents of the burette must be carefully swirled to ensure complete mixing of the contents.

2.5.10 Check the appearance of the final infusion for absence of particles, cloudiness or discolouration. Discard or seek further guidance if unsure whether to proceed.

2.5.11 Label the infusion (see 2.7).

2.6 Diluting a medicine in a syringe for use in a pump or syringe-driver

2.6.1 Prepare the medicine in a syringe using one of the methods described above.

2.6.2 Draw the diluent into the syringe to be used for administration by the pump or syringe-driver. Draw in some air (slightly more than the volume of medicine needed) and remove the needle.

2.6.3 Stand the diluent syringe upright. Insert the safety needle of the syringe containing the medicine into the tip of the diluent (administration) syringe and add the medicine to it. Alternatively, a disposable sterile connector may be used to connect two syringes together directly.

2.6.4 Check the following:

- the total volume of injection solution in the syringe is as specified in the prescription and that the infusion can be delivered at the prescribed rate by the administration device chosen;
- the rate of administration is set correctly on the administration device and according to the manufacturer's instructions.

2.6.6 Fit a blind hub to the administration syringe and invert several times to mix the contents.

2.6.7 Remove the blind hub. Tap the syringe lightly to aggregate the air bubbles at the needle end. Expel the air and refit the blind hub.

2.6.8 Carefully check the syringe for cracks and leaks and then label it (see 2.7), especially noting the requirements specific to syringe drivers.

2.6.9 Check that the rate of administration is set correctly on the device before fitting the syringe, priming the administration set and starting the infusion device.

2.7 Labelling injection and infusion containers

2.7.1 All injections should be labelled immediately after preparation, or be readily identifiable, except for syringes intended for immediate push (bolus) administration by the person who prepared them. Under no circumstances should an operator be in possession of more than one unlabelled or readily identifiable syringe at any one time, nor must an unlabelled syringe be fitted to a syringe driver or similar device.

2.7.2 Labels used on injectable medicines prepared in clinical areas should not occlude the volume when attached, and should contain the following information:

- name of the medicine;
- strength;
- route of administration;
- diluent and final volume;

- patient's name;
- expiry date and time;
- name of the practitioner preparing the medicine.

2.7.3 Place the final syringe or infusion and the empty ampoule(s)/vials(s) in a clean plastic tray with the prescription for taking to the patient for administration.

3: Administration of an Injectable Medicine

3.1 Before administering any injection

3.1.1 Check all the following:

- patient's name, hospital/NHS Number or date of birth or address;
- prescriber's signature;
- the approved medicine name;
- the dose and frequency of administration;
- the date and route of administration;
- the allergy status of the patient.

3.1.2 Also check, where relevant:

- brand name and formulation of the medicine;
- concentration or total quantity of medicine in the final infusion container or syringe;
- name and volume of diluent and/or infusion fluid;
- rate *and* duration of administration;
- type of rate-control pump or device(s) to be used;
- the age and weight of any patient under 16 years of age, where relevant;
- date on which treatment should be reviewed.

3.1.3 Check that the medicine is due for administration at that time and has not already been given.

3.1.4 Assemble everything you need including any flushing solution(s) needed.

3.1.5 Wherever possible, two registrants should check medication to be administered intravenously prior to administration, one of whom should be the registrant who then administers the IV solution.

3.1.6 Explain and discuss the procedure with the patient.

3.1.7 Where intravenous infusion solutions are being administered, it is strongly recommended that these should be given via an appropriate infusion device, whenever possible.

3.1.8 Check any infusion already in progress. It should be free of haziness, particles and discolouration.

3.1.9 Check that an appropriate access device is in place. Flush it immediately before and after administration of a medicine, and between doses of different medicines administered consecutively. Also check the administration site for signs of leakage, infection or inflammation. If any of these are present, an appropriate practitioner must re-site the cannula.

3.1.10 All intravenous sites should be checked every time medicines are administered and status recorded on the 'Record of Insertion Devices' on a shift basis. This chart must also be used to record the insertion and removal of all intravenous devices ('VIP Chart').

3.2 Administration of Injections – General

3.2.1 Check infusions. They should be should be free of haziness, particles and discolouration.

3.2.2 Use aseptic (non-touch) technique at all times.

3.2.3 Attach administration sets to infusion containers carefully, on a flat surface and using the technique appropriate to the type of container.

3.2.4 Prime the access device according to local policy immediately before starting an infusion.

3.2.5 Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before re-commencement, the contents of the burette must be carefully swirled to ensure complete mixing.

3.3 After administration

3.3.1 After completion of an intermittent infusion, flush the access device according to local policy.

3.3.2 Ask the patient to report promptly any soreness at the injection site or discomfort of any sort.

3.3.3 Make a detailed record of administration.

3.3.4 Dispose of equipment and sharps promptly and safely following appropriate Trust policy.

Version 1

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Version 2

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Committee	
Review Date :	Date : Feb 2015

Standard Operating Procedures for the Management of Controlled Drugs in Operating Theatres

Introduction

Separate Trust Standard Operating Procedures (SOPs) are in place for the management of controlled drugs in a) wards/departments, b) operating theatres and c) pharmacy departments. These SOPs cover prescribing, requisitioning, receipt, administration and returning of CDs to Pharmacy. The ward and theatres SOPs are available on Q-Pulse. Both SOPs should be read in conjunction with the policy statements laid out in Chapter 5 of the main Trust Medicines Policy and Procedure.

Please refer to Section 6 for additional guidance on the safe prescribing and administration of opioid medicines. These have been added in response to the NPSA Rapid Response Alert (July 08) – 'Reducing Dosing Errors with Opioid Medicines'

1. Prescribing of Controlled Drugs in Operating Theatres

1.1 Prescribing of controlled drugs will be in accordance with the Misuse of Drugs Act (1971) and its associated Regulations, and the Medicines Act (1968). Additional statutory measures for the management of CDs are laid down in the Health Act (2006) and its associated Regulations.

1.2 The Misuse of Drugs (Supply to Addicts) Regulations 1997 prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

1.3 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on in-patient prescription forms for in patient use. Medical doctors who have not achieved full registration with the GMC are <u>not</u> permitted to prescribe CDs for discharge prescriptions or for outpatients.

1.4 Non-medical prescribers are only permitted to prescribe those CDs that they are legally entitled to prescribe.

1.5 CDs must be prescribed on the in-patient prescription chart or the anaesthetics card. Where separate charts are used e.g. anaesthetic charts they should be cross-referenced on the main patients drug chart.

1.6 The written requirements for controlled drugs on these charts are the same as for other medicines:

- Drug name and form
- Route
- Dose
- Frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24hrs)
- Include a finish time/date where appropriate
- Start date
- Signature of prescriber

The patient's name, unit number and allergy status should also be written on the chart.

2. Requisitioning of Controlled Drugs for Operating Theatres

2.1 The registered nurse or midwife in charge of an operating theatre or theatre suite is responsible for the requisitioning of CDs for use in that area. Even if the ward or department is managed by someone other than a nurse, the most senior registered nurse or midwife present is responsible for controlled drugs under the present Regulations.

2.2 The registered nurse or midwife in charge can delegate the task of preparing a requisition to another, such as a registered nurse or registered operating department practitioner (ODP). However, legal responsibility remains with the registered nurse or midwife in charge.

2.3 Orders for CDs must be made in the approved Trust Controlled Drugs Order Book using a separate page for each item and signed (plus printed name) by an authorised signatory. Order books should be kept in a safe place in the theatre to avoid misappropriation of controlled drugs.

2.4 An up to date list of authorised signatories for the ordering of controlled drugs must be kept in the theatre and in the Pharmacy Departments. It will be the responsibility of the theatre manager to maintain each list and only staff on the list will be able to order controlled drugs.

2.5 Requisitions must contain the following:

- Name of hospital
- Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature and printed name of registered nurse
- Date

2.6 Ideally, orders for CDs should reach the pharmacy by 11am each weekday morning for delivery in the afternoon. Completed order books must be delivered by hand to pharmacy staff i.e. **not** sent through the internal mail. Orders on a Saturday must be for urgent items only.

3. Receipt of Controlled Drugs in Operating Theatres

3.1 CDs will normally be delivered to the theatre by a member of staff authorised by the Pharmacy Department who will sign the top copy which will be retained by the Pharmacy.

3.2 If CDs are needed urgently between delivery rounds a responsible representative from the ward, nominated by the theatre manager, may collect them directly from the pharmacy. Staff collecting CDs from the Pharmacy must display valid ID.

3.3 In each case, the registered health care practitioner who receives the controlled drugs must check the CDs against the requisition – including the number ordered and received. Any tamper-evident seals on packs should be left intact when they are received from pharmacy, this will simplify and speed up routine checks.

3.4 If a discrepancy exists between the order and the CDs delivered/collected, the Pharmacy Department must be contacted <u>immediately.</u>

3.5 If the order is correct, the order book must be signed in the presence of the messenger. The order book will then stay on the theatre.

3.6 Theatres are required to use special 'Theatre Controlled Drug Record Books' (and not 'Ward Controlled Drug Record Books') to record receipts and issues of controlled drugs. These are available from the Pharmacy Departments.

3.7 As soon as possible, after receipt of the CDs from the pharmacy, details of stock delivered/collected must be entered into the appropriate sections of the Theatre CD Record Book.
There should be a separate Theatre CD record book for each theatre.
The details to be entered into the appropriate page on the register are:

- Date
- Quantity Received
- Serial Number of Requisition
- Signature of Person making the Entry
- New Stock Balance

3.8 It is advisable at this stage to check the new balance tallies with the quantity that physically exists in the theatre.

3.9 The received CDs should be placed in the CD cupboard.

3.10 As a general rule it is good practice that the receiving person should not be the same person who ordered the CDs. It is also good practice that receipt of CDs and updating of the Theatre CD Record Book is witnessed by a second competent professional wherever possible.

4. Administration of Controlled Drugs in Operating Theatres

4.1 The administration of CDs should comply with all local policies and procedures for the administration of medicines (see Chapter 4 of The Trust Medicines Policy). Nurses and midwives must follow Nursing and Midwifery standards and guidance.

4.2 The administration of controlled drugs must be double checked by a second practitioner throughout the whole of the administration process and this checker must act as a second signatory in all documentation.

4.3 Where two practitioners are involved in the administration of CDs, one of them must be a registered practitioner i.e. nurse, midwife, doctor or ODP. Both practitioners should be present during the whole of the administration procedure.

4.4 In line with the administration of all medicines the following procedure should be followed when administering CDs :

a) Read the prescription chart carefully. If there is any doubt about the legibility of the prescription or other particulars such as dosage, route, time or frequency of the administration of the medicine, the nurse or midwife should check with the prescriber concerned or the pharmacist.
b) Check that the prescribed dose has not already been administered.
c) Select the medicine required and check the following: -
   - the medicine (name, strength and formulation) with the prescription
   - the calculation, if any
   - the measured dose
   - the correct time
   - the correct route
   - appropriate storage;
   - the expiry date;
   - the validity of the prescription
   - any known allergies.
d) Take the measured dose and prescription chart to the patient.
e) Positively identify the in-patient using the patient name-band, and other patients by asking the patient to state his/her name and date-of-birth.
f) Administer the medication to the patient.
g) In the case of oral medication, ensure the medicine has been swallowed.
h) Sign for the administration or enter the details of non-administration in the appropriate place on the prescription chart.

4.5 For CDs administered, the following details should be recorded in the appropriate page of the Theatre CD Record Book, and countersigned by the checker:

- Date and time when dose administered
- Name of patient
- Quantity administered
- Name/Signature of person who administered the dose
- Name/Signature of witness (where there is one)
- Balance left in stock after administration

4.6 Substances prepared for administration and subsequently not used must be disposed of in an appropriate manner (see 4.8) in the presence of a second person who may be a pharmacist, nurse or doctor. They must not be returned to the containers from which they were removed; the details must be entered in the appropriate section of the Theatre CD Record Book.

4.7 The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the Theatre CD Record Book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006. www.aagbi.org*] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed.

4.8 If part of a vial is administered to a patient, the registered nurse, midwife or registered health professional should record the amount supplied, the amount administered and the amount destroyed in the appropriate column of the Theatre CD Record Book, e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*5mg supplied, 2.5mg administered*, *2.5mg destroyed*". This should be witnessed by a second registered nurse midwife or registered health professional who should also sign the record. If a second registered nurse midwife or registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant. The unused/wasted portion of the dose should be disposed of as in 4.9.

4.9 Small amounts of CDs can be destroyed and rendered irretrievable by emptying into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

4.10 Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.

4.11 A separate policy exists within theatres for the management of all aspects of patient controlled analgesia.

5. Returning Controlled Drugs to Pharmacy

5.1 Unused CD stock or stock no longer required in theatres should be returned to the pharmacy. Such CD stock can be re-issued by the pharmacy provided it was initially issued by that pharmacy and has at all times been under the control of that hospital. The pharmacy department will carry out a risk assessment of CDs returned to pharmacy to ensure they are fit for re-use.

5.2 CDs that are time-expired or otherwise unfit for use should also be returned to the pharmacy for safe destruction and onward disposal. Any other controlled drug that is no longer needed in theatres should be returned to pharmacy. This should be done as soon as is practicable.

5.3 In the event of a theatre wishing to return CDs to the Pharmacy for any of the above reasons, the local Pharmacy Department should be contacted either by telephone. A pharmacist will then attend the theatre and assist and witness the return transaction. Alternatively, a member of theatre staff nominated by the theatre manager may bring stock for return to the Pharmacy along with the Theatre CD Record Book to the Pharmacy in order to record the details.

5.4 Details of CDs returned to Pharmacy must be recorded in the Theatre CD record book. An entry should be made in the appropriate page showing:

- Date CD Returned
- Reason for Return
- Quantity Returned
- Name/Signature of Responsible Person on the Ward
- Name/Signature of witness (usually pharmacist)
- Balance left in stock after removal of returned CDs

5.5 The pharmacist will then arrange for the CDs to be transferred to the Pharmacy in a safe and secure way.

6. Safe Prescribing and Administration of Opioid Medicines

6.1 Many incidents are reported to the National Reporting and Learning System (NRLS) concerning patients receiving unsafe doses of opioid medicines, where a dose or formulation was incorrect, based on the patient's previous opioid dose.

6.2 Every member of the team has a responsibility to check that the intended dose is safe for the individual patient. Knowledge of previous opioid dose is essential for the safe use of these products. There is a wide variety of opioid medicines, and supply shortages may result in products being used which are unfamiliar to practitioners.

6.3 When opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, the healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the

patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.

- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not **normally** more than 50% higher than the previous dose).
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

6.4 While dose increments should be in line with this guidance, it is recognised that in palliative care higher than normal doses may be required. These recommendations are not designed to restrict clinical use of opioid medicines, but to ensure they are used in a way that is as safe as possible for patients**.**

6.5 Usual starting doses for opioid medicines may vary depending on the type of patient e.g. doses in paediatric patients are likely to be very different to those in adult patients. Information relating to starting doses, dose conversion and formulations may be found in the following texts (other texts may also be relevant):

- British National Formulary (Individual product monographs and 'Prescribing in Palliative Care' section)
- British National Formulary for Children
- Palliative Care Formulary or www.palliativedrugs.com
- Summary of Product Characteristics (SPC) of individual products

6.6 The NPSA have produced a set of algorithms which may be helpful for staff in reducing risks of dosing errors with opioid medicines. These are available at:

http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/reducing-dosing-errors-with-opioid-medicines/

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Standard Operating Procedures for the Management of Controlled Drugs in Wards and Departments

Introduction

Separate Trust Standard Operating Procedures (SOPs) are in place for the management of controlled drugs in a) wards/departments, b) operating theatres and c) pharmacy departments. These SOPs cover prescribing, requisitioning, receipt, administration and returning of CDs to Pharmacy. The ward and theatres SOPs are available on Q-Pulse. Both SOPs should be read in conjunction with the policy statements laid out in Chapter 5 of the main Trust Medicines Policy and Procedure.

Please refer to Section 6 for additional guidance on the safe prescribing and administration of opioid medicines. These have been added in response to the NPSA Rapid Response Alert – 'Reducing Dosing Errors with Opioid Medicines'

6. Prescribing of Controlled Drugs

1.1 General Principles

1.1.1 Prescribing of controlled drugs will be in accordance with the Misuse of Drugs Act (1971) and its associated Regulations, and the Medicines Act (1968). Additional statutory measures for the management of CDs are laid down in the Health Act (2006) and its associated Regulations.

1.1.2 The Misuse of Drugs (Supply to Addicts) Regulations 1997 prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

1.1.3 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on in-patient prescription forms for in patient use. Medical doctors who have

not achieved full registration with the GMC are not permitted to prescribe CDs for discharge prescriptions or for outpatients.

1.1.4 Non-medical prescribers are only permitted to prescribe those CDs that they are legally entitled to prescribe.

1.2 Prescribing for In-patients

1.2.1 For hospital inpatients, CDs must be prescribed on the in-patient prescription chart or the anaesthetics card.

1.2.2 The written requirements for controlled drugs on these charts are the same as for other medicines:

- Drug name and form
- Route
- Dose
- Frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24hrs)
- Include a finish date where appropriate
- Start date
- Signature of prescriber

The patient's name, unit number and allergy status should also be written on the chart.

1.3 Prescribing for Discharge Patients

1.3.1 Prescriptions for CDs for patients who are going home (discharge medicines) should be added to the patient's Electronic Discharge Prescription (EDN) along with any other medication. Beside the CD entry on the EDN a red icon will appear which directs the prescriber to a separate 'Controlled Drug Discharge Prescription' sheet with the patient details already filled in. This must be printed out and the area that requires handwritten details (e.g. dosage form, strength, instructions and total quantity to be dispensed in words and figures) completed by the prescriber. The prescriber must also sign and date this prescription.

This completed sheet will be required by the Pharmacy dept. to allow them to legally dispense the CDs on the EDN.

1.4 Prescribing for Out-Patients

1.4.1 Prescriptions for CDs for out-patients can either be written on hospital out-patient prescription forms or a hospital FP10 prescription for a community pharmacy to dispense.

These prescriptions must conform to all handwriting requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 1.5).

1.5 Handwriting Requirements for Controlled Drugs (Out-Patients/Discharge)

1.5.1 A prescription for Schedule 2 and 3 CDs (with the exception of temazepam and midazolam preparations) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated.

- The patient's full name, address and, where appropriate, age
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures

1.5.2 The prescription must be signed by the prescriber with his/her usual signature, in his own handwriting (this must be handwritten) and dated by him/her (the date does not have to be handwritten).

7. Requisitioning of Controlled Drugs for Wards and Departments

2.1 The registered nurse or midwife in charge of a ward or department is responsible for the requisitioning of CDs for use in that area. Even if the ward or department is managed by someone other than a nurse, the most senior registered nurse or midwife present is responsible for controlled drugs under the present Regulations.

2.2 The registered nurse or midwife in charge can delegate the task of preparing a requisition to another, such as a registered nurse. However, legal responsibility remains with the registered nurse or midwife in charge.

2.3 Orders for CDs must be made in the approved Trust Controlled Drugs Order Book using a separate page for each item and signed (plus printed name) by an authorised signatory. Order books should be kept in a safe place on the ward to avoid misappropriation of controlled drugs.

2.4 An up to date list of authorised signatories for the ordering of controlled drugs must be kept on the ward/department and in the Pharmacy Departments. It will be the responsibility of the ward/ department manager to maintain each list and only staff on the list will be able to order controlled drugs.

2.5 Requisitions must contain the following:

- Name of hospital
- Ward / Department
- Drug name, form, strength, ampoule size if more than one available

- Total quantity
- Signature and printed name of registered nurse
- Date

2.6 Ideally, orders for CDs should reach the pharmacy by 11am each weekday morning for delivery in the afternoon. Completed order books must be delivered by hand to pharmacy staff i.e. **not** sent through the internal mail. Orders on a Saturday must be for urgent items only.

8. Receipt of Controlled Drugs in Wards and Departments

3.1 CDs will normally be delivered to the ward/department by a member of staff authorised by the Pharmacy Department who will sign the top copy which will be retained by the Pharmacy.

3.2 If CDs are needed urgently between delivery rounds a responsible representative from the ward, nominated by the ward manager, may collect them directly from the pharmacy. Staff collecting CDs from the Pharmacy must display valid ID.

3.3 In each case, the registered health care practitioner who receives the controlled drugs must check the CDs against the requisition – including the number ordered and received. Any tamper-evident seals on packs should be left intact when they are received from pharmacy, this will simplify and speed up routine checks.

3.5 If a discrepancy exists between the order and the CDs delivered/collected, the Pharmacy Department must be contacted <u>immediately.</u>

3.5 If the order is correct, the order book must be signed in the presence of the messenger. The order book will then stay on the ward.

3.6 As soon as possible, after receipt of the CDs from the pharmacy, details of stock delivered/collected must be entered into the appropriate sections of the CD Record Book.

The details to be entered into the appropriate page on the register are:

- Date
- Quantity Received
- Serial Number of Requisition
- Signature of Person making the Entry
- New Stock Balance

3.7 It is advisable at this stage to check the new balance tallies with the quantity that physically exists on the ward.

3.8 The received CDs should be placed in the CD cupboard.

3.9 As a general rule it is good practice that the receiving person should not be the same person who ordered the CDs. It is also good practice that receipt of CDs and updating of the CD Record Book is witnessed by a second competent professional wherever possible.

9. Administration of Controlled Drugs

4.1 The administration of CDs should comply with all local policies and procedures for the administration of medicines (see Chapter 4 of The

Trust Medicines Policy). Nurses and midwives must follow Nursing and Midwifery standards and guidance.

4.2 The administration of controlled drugs must be double checked by a second practitioner throughout the whole of the administration process and this checker must act as a second signatory in all documentation.

4.3 Where two practitioners are involved in the administration of CDs, one of them must be a registered practitioner i.e. nurse, midwife or doctor. Both practitioners should be present during the whole of the administration procedure.

4.4 In line with the administration of all medicines the following procedure should be followed when administering CDs :

i) Read the prescription chart carefully. If there is any doubt about the legibility of the prescription or other particulars such as dosage, route, time or frequency of the administration of the medicine, the nurse or midwife should check with the prescriber concerned or the pharmacist.
j) Check that the prescribed dose has not already been administered.
k) Select the medicine required and check the following: -
   - the medicine (name, strength and formulation) with the prescription
   - the calculation, if any
   - the measured dose
   - the correct time
   - the correct route
   - appropriate storage;
   - the expiry date;
   - the validity of the prescription
   - any known allergies.
l) Take the measured dose and prescription chart to the patient.
m) Positively identify the in-patient using the patient name-band, and other patients by asking the patient to state his/her name and date-of-birth.
n) Administer the medication to the patient.
o) In the case of oral medication, ensure the medicine has been swallowed.
p) Sign for the administration or enter the details of non-administration in the appropriate place on the prescription chart.

4.5 A record must be made in the ward or department CD Record Book when a CD is removed from the CD cupboard for the purposes of administration and countersigned by the checker.

4.6 For CDs administered, the following details must be recorded in the appropriate page of the CD Record Book :

- Date and time when dose administered
- Name of patient
- Quantity administered
- Name/Signature of person who administered the dose

- Name/Signature of witness (where there is one)
- Balance left in stock after administration

4.7 Substances prepared for administration and subsequently not used must be disposed of in an appropriate manner (see 4.8) in the presence of a second person who may be a pharmacist, nurse or doctor. They must not be returned to the containers from which they were removed; the details must be entered in the appropriate section of the CD Record Book.

4.8 If part of a vial is administered to the patient, the registered nurse, midwife or registered health professional should record the amount given and the amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* ". This should be witnessed by a second registered nurse midwife or registered health professional who should also sign the record. If a second registered nurse midwife or registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant. The unused/wasted portion of the dose should be disposed of as in 4.9

4.9 Small amounts of CDs can be destroyed and rendered irretrievable by emptying into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

10. Returning Controlled Drugs to Pharmacy

5.1 Unused CD stock or stock no longer required in wards or departments may be returned to the pharmacy. Such CD stock can be re-issued by the pharmacy provided it was initially issued by that pharmacy and has at all times been under the control of that hospital. The pharmacy department will carry out a risk assessment of CDs returned to pharmacy to ensure they are fit for re-use.

5.2 CDs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal. Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable.

5.3 In the event of the ward or department wishing to return CDs to the Pharmacy for any of the above reasons, the local Pharmacy Department should be contacted either by telephone or via any of the Pharmacy ward staff. A pharmacist will then attend the ward and assist and witness the return transaction. Alternatively, a member of the ward staff nominated by the ward manager may bring stock for return to the Pharmacy along with the CD Record Book to the Pharmacy in order to record the details.

5.4 Details of CDs returned to Pharmacy must be recorded in the ward CD record book. An entry should be made in the appropriate page showing:

- Date CD Returned
- Reason for Return
- Quantity Returned
- Name/Signature of Responsible Person on the Ward
- Name/Signature of witness (usually pharmacist)
- Balance left in stock after removal of returned CDs

5.5 The pharmacist will then arrange for the CDs to be transferred to the Pharmacy in a safe and secure way.

6. Safe Prescribing and Administration of Opioid Medicines

6.3 Many incidents are reported to the National Reporting and Learning System (NRLS) concerning patients receiving unsafe doses of opioid medicines, where a dose or formulation was incorrect, based on the patient's previous opioid dose.

6.4 Every member of the team has a responsibility to check that the intended dose is safe for the individual patient. Knowledge of previous opioid dose is essential for the safe use of these products. There is a wide variety of opioid medicines, and supply shortages may result in products being used which are unfamiliar to practitioners.

6.3 When opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, the healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not **normally** more than 50% higher than the previous dose).
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

6.6 While dose increments should be in line with this guidance, it is recognised that in palliative care higher than normal doses may be required. These recommendations are not designed to restrict clinical use of opioid medicines, but to ensure they are used in a way that is as safe as possible for patients.

6.7 Usual starting doses for opioid medicines may vary depending on the type of patient e.g. doses in paediatric patients are likely to be very different to those in adult patients. Information relating to starting doses, dose

conversion and formulations may be found in the following texts (other texts may also be relevant):

- British National Formulary (Individual product monographs and 'Prescribing in Palliative Care' section)
- British National Formulary for Children
- Palliative Care Formulary or www.palliativedrugs.com
- Summary of Product Characteristics (SPC) of individual products

6.6 The NPSA have produced a set of algorithms which may be helpful for staff in reducing risks of dosing errors with opioid medicines. These are available at : http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/reducing-dosing-errors-with-opioid-medicines/

Version 1

SOP Prepared by *: Jim Reside, Chief Pharmacist*	Date : Oct 2007
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Version 2

SOP Updated by *: Jim Reside, Chief Pharmacist*	Date : Oct 2009
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Version 3

SOP Updated by *: Jim Reside, Chief Pharmacist*	Date : Jun 2013
SOP Approved by : *Medicines Management Committee*	Date : Jul 2013
Review Date :	Date : Feb 2015

Current policies and procedures:

Critical Medicines Where Timeliness of Administration is Crucial

It is important to recognise that harm can arise from the omission or delay of the administration of a medicine and, if that medicine is critical (e.g. insulin, antibiotics, anticoagulants) the consequences can be serious or even fatal.

The Trust expects that all staff should endeavour to prescribe and administer all medicines in a timely manner.

The NPSA Alert 2010/RRR009 highlighted the risks to patient safety of omitted or delayed doses. As part of the recommendations from this document a list of 'critical' medicines where timeliness of administration is crucial was recommended. This list is available on Q-Pulse.

Due to the risk of patient harm, prescription, dispensing and administration of the following drugs must never be unintentionally omitted or delayed.

Omission or delay of these drugs constitutes an adverse incident and is reportable to the NPSA.

Definitions

Omission = Failure to prescribe a drug in a timely manner
Failure to administer a dose before the next dose is due or, in the case of once only doses, failure to administer a drug within one hour of the time the dose is due

Delay = Administration of a drug one hour or more after the time the dose is due (may be less for some drugs or indications – see list)

Drug name or class	Rationale for inclusion

Systemic antimicrobials (including antibiotics, antifungals, antivirals and antimalarials) within the first 48 hours of therapy	Potential worsening of systemic infection and deterioration of condition
Gentamicin in neonates must be given within 1 hour of the time the dose is due	Requirement of NPSA/2010/PSA001 Safer Use of intravenous gentamicin for neonates
Antiretrovirals	Potential for emergence of viral resistance
Insulin	Poor glycaemic control and potential for symptomatic hyperglycaemia
Oral hypoglycaemic agents	Poor glycaemic control and potential for symptomatic hyperglycaemia
Glucose/glucagon	Failure to treat symptomatic hypoglycaemia (medical emergency) with risk of patient harm
Opiates prescribed regularly for the management of severe chronic pain. Includes regular oral therapy, parenteral therapy and transdermal therapy	Loss of pain control. Increased need for intermittent analgesic doses
Naloxone	Failure to treat opiate toxicity (medical emergency) with risk of patient harm
Immunosuppressants for transplant patients	Risk of transplant rejection due to sub therapeutic levels
Chemotherapy, including cytotoxics and adjunctive therapies prescribed as part of an approved chemotherapy regimen	Delay in treatment and disruption of chemotherapy regimen scheduling. Treatment failure
Drug name or class	**Rationale for inclusion**
Corticosteroids	Treatment failure in acute conditions. Risk of Addisonian crisis in steroid dependency
Anticoagulants (therapeutic)	Progression of thrombus and risk of serious embolic episode (stroke/PE)
Anticoagulants (thromboprophylaxis)	Risk of thrombus and serious embolic episode
Parenteral electrolyte replacement (including potassium, calcium, magnesium, phosphate) for the urgent treatment of symptomatic deficiencies	Deterioration in clinical condition
Calcium resonium, glucose/insulin	Emergency treatment of symptomatic hyperkalaemia
Parenteral **bisphosphonates** in the treatment of severe symptomatic hypercalcaemia	
Glucose infusions in normoglycaemic patients receiving intravenous insulin infusions	Risk of hypoglycaemia

Drugs administered as **prophylactic agents** to reduce toxicity of other drugs e.g. phenytoin/busulphan, chlorphenamine and hydrocortisone/Campath, acetylcysteine/contrast media	Increased risk of adverse drug events with known toxic medicines
Antiepileptic agents	Loss of seizure control
Anti-Parkinsonian agents	Loss of symptom control. 'Get it on time' campaign
Nebulised **bronchodilator** therapy	Deterioration in clinical condition
Resuscitation drugs and reversal agents including **plasma expanders**	Failure to treat medical emergencies with risk of patient harm
Antiplatelets and thrombolytics	Increased risk of poor outcomes following MI Risk of re-stenosis in patients undergoing PCI
Beta-blockers perioperatively	May cause tachyarrhythmias
Analgesics for the management of post-operative pain	Patient experiences avoidable pain
Benzodiazepines and parenteral vitamins for the management of acute alcohol withdrawal syndromes	
Oxygen	Increased risk of harm from prolonged hypoxia

References

NPSA Rapid Response Alert (NPSA/2010/RRR009) 'Reducing Harm from Omitted and Delayed Medicines in Hospital'

King's College Hospital Omitted Medicines List

Critical Medicines With Loading Doses Likely to Cause Harm

A loading dose is an initial large dose of a medicine used to ensure a quick therapeutic response. It is usually given for a short period before therapy continues with a lower maintenance dose. The use of loading doses of medicines can be complex and error prone. Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death.

The Trust expects that all staff should endeavour to prescribe and administer loading and maintenance doses safely and correctly.

The NPSA Alert 2010/RRR018 highlighted the risks to patient safety of incorrect loading doses, omitted or delayed administration of loading doses, or unintentional continuation of loading doses. As part of the recommendations a risk assessment was carried out to identify a list of critical medicines where accurate loading dose prescribing and administration is crucial. This list is available on Q-Pulse.

Due to the risk of patient harm these must be effective communication regarding loading dose and subsequent maintenance dose regimens when prescribing, dispensing and administering critical medicines. Clinical checks should be performed by medical, nursing and pharmacy staff (when available) to ensure loading and maintenance doses are correct.

Critical Medicines

- Amiodarone
- Aminophylline
- Phenytoin
- Warfarin
- Digoxin
    - Heparin
    - Potassium

- Alteplase
- Danaparoid
- Infliximab
- Lidocaine
- Teicoplanin
- Tirofiban

See below for more information about each of the critical drugs identified.

PRESCRIBING INFORMATION FOR THE ADMINISTRATION OF AMIODARONE IN ADULT PATIENTS

7. Loading Dose (when required)

A loading dose of 300mg shoule be given as an IV Infusion of:

- 300mg Amiodarone in 100ml Glocose 5% over 30 minutes

For **Emergency Control ONLY** a slow IV bolus may be used.

8. Maintenance Infusion

- Amiodarone 900mg in 500mL Glucose over 24 hours (21mL/hr)

This may be continued as necessary according to response and clinical condition.

9. Administration Guidance

Administer centrally e.g. via long line (to avoid thrombophlebitis).

Amiodarone is an irritant to veins. The vascular access site should be regularly checked for any signs of irritation (redness, pain and swelling). The vascular access should be re-sited should any irritation occur.

10. Interactions

Amiodarone can interact with many drugs. All concurrent medications should be assessed for potential interactions when amiodarone is started. Some clinically important interactions include:

- ***Warfarin*** – the anticoagulant effect of warfarin will be increased in most people treated with amiodarone. Maximal effect occurs between two and seven weeks after starting treatment with amiodarone. Monitor INR closely during this period.
- ***Digoxin*** – digoxin levels can be approximately doubled. Monitor digoxin levels and consider halving the digoxin dose.
- ***Simvastatin*** – doses above 20mg should not be used with amiodarone because of increased risk of myopathy.
- ***Phenytoin*** – phenytoin levels can be markedly raised in patients taking amiodarone. Monitor phenytoin levels closely and reduce dose as necessary.

11. Converting from IV to Oral

If the decision is taken to continue amiodarone long term the following regimen should be followed.

Continue the infusion for 12 hours after the first oral dose

- 200-400mg THREE times a day for 7 days then
- 200-400mg TWICE a day for 7 days
- 200-400mg ONCE a day thereafter

12. Monitoring

Monitor liver and thyroid function for patients on long term therapy. The patient should have a baseline and 6 monthly LFT and TFT. Patients should also have a baseline chest x-ray which should be repeated if the patient experiences unexplained dyspnoea or non-productive cough as amiodarone can cause pneumonitis, fibrosis and pleuritis.

PRESCRIBING INFORMATION FOR THE ADMINISTRATION OF AMINOPHYLLINE

7. Patients already taking oral theophylline or aminophylline

A loading dose must **NOT** be given.

8. Patients NOT already taking oral theophylline or aminophylline

A loading dose should be given

The patient's weight should be known before the drug is prescribed [in an emergency an estimate can be accepted until patient can tell you their weight or be weighed]

Loading dose = 5mg/kg *(as an IV infusion in 100ml sodium chloride 0.9% or glucose 5% over 20 minutes). Maximum infusion rate = 25mg / minute*

9. Maintenance Infusion

Aminophylline 1g in 1L of sodium chloride 0.9% (preferred choice) or glucose 5%.

The initial rate of infusion (mL/hour) can be calculated using the table overleaf.

10. Drug Interactions

Theophylline is metabolised by the liver. Therefore drugs that inhibit or induce hepatic enzymes will affect theophylline clearance.

CIPROFLOXACIN, ERYTHOMYCIN AND CLARITHROMYCIN decrease theophylline clearance and can therefore lead to toxicity - *the rate of aminophylline infusion should be* ***HALVED***

There are many other drugs that interact with theophylline – *Please refer to the BNF.*

11. Measuring Theophylline and Potassium Levels

The therapeutic range for theophylline is: 10 – 20 mg/L

Theophylline *(not aminophylline)* is measured, as this is the active constituent of the drug.

When should the level be checked first?

If a loading dose has been given:	**6 hours** after starting the infusion.
If toxicity is a risk:	**6 hours** after starting the infusion.
All other patients:	**12-18 hours** after starting the infusion.

Repeat levels **MUST** be taken **every 24 hours.**

Infusion rates may be adjusted using the equation:

$$\textit{New Infusion Rate} = \frac{\textit{15 x Current Infusion Rate}}{\textit{Current Theophylline Level (mg/L)}}$$

The patient's potassium levels should be checked within 12 hrs of starting an infusion (and as necessary thereafter)

12. Converting from IV to Oral

- When converting from aminophylline to theophylline, a conversion factor is necessary. Aminophylline contains 80% theophylline, therefore the conversion factor = 0.8.
- When converting to oral aminophylline, there is no need for a conversion factor.
- Give the first oral dose as the rate of aminophylline infusion is reduced to zero over 8-12 hours.
- A 6 – 8 hour post-dose level **MUST** be taken after 2 days.

Example	
60kg patient, rate of infusion	= 30ml/hour
Total daily dose	= 720mg of aminophylline (of which 80% is theophylline)
Therefore dose of theophylline	= 720mg x 0.8 = 576mg
Give the nearest practical dose	= Uniphyline Continuous® 300mg bd

Consult the formulary of *BNF* for aminophyllne / theophylline preparations available.

Dosing Information for Intravenous Phenytoin in Status Epilepticus in Adults

Preparation: Vials contain 250mg phenytoin in 5ml

Single Loading dose: **20mg/kg** *(from BNF 62)*

LOADING DOSE

Clinician to decide whether actual or ideal body weight should be used

Weight (kg)	Loading dose (mg)	Volume of Phenytoin (mL)	Volume of Sodium Chloride 0.9% (mL)	Infusion time (minutes)
36-41	800	16	100	30-60
42-46	900	18	100	30-60
47-52	1000	20	100	30-60
53-57	1100	22	250	60
58-63	1200	24	250	60
64-69	1300	26	250	60
70-74	1400	28	250	60
75-80	1500	30	250	60
81-85	1600	32	250	60
86-91	1700	34	250	60
92-96	1800	36	250	60
97 upwards	1900	38	250	60

How do I administer an infusion of phenytoin?	Add the phenytoin to the volume of sodium chloride 0.9% in the table. Infusions containing greater than 10mg/ml Phenytoin are likely to precipitate during use and should be avoided. **Infusion time -** See table. The max rate of administration in an adult is 50mg per minute. Because of the risk of precipitation always use an infusion line incorporating a 15 micron filter.
Who supplies these infusion lines?	15 micron filter lines suitable for a Graseby 500 pump can be obtained from pharmacy. Clinical areas that shock phenytoin should consider keeping a small supply of these lines.

MAINTENANCE DOSE

Maintenance dose:

Initially: 100mg every 6-8hours (usually start with 100mg three times a day)

Dose may be lower in patients with low albumin levels or in patients receiving other medicines which interact with phenytoin. Contact your pharmacist for advice about interactions between medications.

How do I administer a maintenance dose of phenytoin?	Best practice is to administer a bolus dose of 100mg over 3 – 5 minutes, but dose can be administered as an infusion. **Once a phenytoin level has been recorded:** Dose should be adjusted according to the serum phenytoin level. See below for advice on timing of samples and monitoring.

Continued overleaf

Therapeutic drug monitoring: Target phenytoin level is 10-20 mg/L*
*(* Level is different in patients prescribed sodium valproate – 5-10mg/L)*

When do I take levels?	**After loading dose:** Phenytoin levels should eb taken **between 6 - 24 hours** after loading dose has been given. This level will guide to assess whether therapeutic range has been achieved.
	After maintenance dose: This depends on the clinical situation. If a patient is poorly controlled or there are concerns about absorption levels should be taken once of twice a week (or more often). For non-acute cases, particularly those managed as out-patients, levels should be taken **2 – 3 weeks** after treatment initiated or if the dose has not been changed. A trough level is required before the morning dose. Levels may also be need to be taken more frequently in malnourished patients, patients with liver impairment or patients taking medicines which interact with phenytoin. The pharmacokinetics of phenytoin mean that a small dose increase can produce a large increase in phenytoin levels. If a dose increase is required dosages should be changed in small increments only to avoid toxicity. Contact a pharmacist or neurologist for advice regarding adjusting phenytoin doses.

Other monitoring:

Parameters:	BP, ECG, O_2 saturation and respiratory rate
Signs of phenytoin toxicity	The initial symptoms are ataxia, lethargy, slurred speech, nausea and vomiting. The patient may become comatose.

Converting to oral phenytoin

Convert to oral preparation when patient is able to tolerate oral feeds. Give total daily dose as a single dose. Formulations of phenytoin are not bio-equivalent.	
Converting from Intravenous dose to oral dose when patient can swallow capsules	Total daily intravenous dose is equal to total daily oral dose
Converting from Intravenous dose to oral dose when patient requires suspension	If daily intravenous dose is 300mg then daily oral liquid dose is 270mg Phenytoin suspension interacts with enteral feeds causing decreased absorption. Phenytoin should **NEVER** be administered via enteral feeding tube. Continue intravenous injection

Warfarin

Please refer to trust formulary for the Medicines Information Frequently asked Questions section on Anticoagulants for guidance on warfarin loading and prescribing.

Digoxin

Please refer to trust formulary for the section on cardiac glycosides and therapeutic drug monitoring for digoxin loading and prescribing guidance.

Drug	**Digoxin**
Signs of toxicity	Nausea & vomiting Diarrhoea Visual disturbances Confusion Delirium
To calculate dose	**14 microgram/kg oral loading** **10 microgram/kg IV loading** **Maintenance – 125 microgram or less with reduced renal function or low body weight**
What alters dosage	Renal function Weight Amiodarone (reduce dose by half)
Obesity - how to change dosage	Calculate on ideal body weight
Target range for drug levels	0.5-1.0 microgram/l
Take levels on	7 days
When to sample	6-11 hrs post-dose

Heparin

Please refer to trust formulary for the Medicines Information Frequently asked Questions section on Anticoagulants for guidance on heparin loading and prescribing.

Potassium

Please refer to trust formulary for the therapeutic section on Fluid and Electrolytes for guidance on potassium prescribing.

Alteplase

Please refer to trust formulary for the Therapeutic section on Fibrinolytics and the prescribing guidelines section for “Guidelines for effective management of TIA and Stroke” to find information about alteplase prescribing.

Danaparoid

Please refer to trust formulary for the Medicines Information Frequently asked Questions section on anticoagulation for guidance on danaparoid prescribing.

Infliximab

Please refer to trust formulary for the Therapeutic section on Chronic Bowel Disorders, Drugs Used in Rheumatic Disease & Gout and preparations for Eczema & Psoriasis for information about infliximab prescribing.

Lidocaine

Please refer to trust formulary for the Therapeutic section on Anti-arrhythmic drugs and local anaesthesia for guidelines about lidocaine prescribing.

Teicoplanin

Please refer to trust formulary for the Therapeutic section on Other Antibacterials for guidelines about teicoplanin prescribing.

Tirofiban

Please refer to trust formulary for the Therapeutic section on Antiplatelet Drugs for guidelines about tirofiban prescribing.

Standard Operating Procedure for Prescribing, Preparing and Administering Injectable Medicines in Clinical Areas

Please note that these procedures EXCLUDE the prescription, supply and administration of INTRATHECAL chemotherapy which is subject to a separate policy

Introduction

The use of injectable medication has many healthcare benefits for patients. The complexities associated with the prescription, preparation and administration of injectable medicines means that there are greater potential risks for patients than for other routes of administration. Weak operating systems increase the potential risk of harm, and safe systems of work are needed to minimise these risks.

These procedures refer to all injectable medicines routes (except intrathecal), however more specialist routes e.g. sub-conjunctival etc. may be subject to additional and more specific guidance.

This Trust Standard Operating Procedure for Prescribing, Preparing and Administering Injectable Medicines in Clinical Areas forms part of the Trust Medicines Policy and should be read in conjunction with Chapter 6 of that policy.

This document has been written incorporating guidance from the NPSA 'Promoting Safer Use of Injectable Medicines' documents.

1: Prescribing

1.2 All prescriptions for injectable medicines, where relevant (and including those items prepared aseptically within the Pharmacy Departments), must specify the following:

- the approved medicine name;
- the dose and frequency of administration;
- the date and route of administration;
- the date on which treatment should be reviewed;
- the prescriber's signature;

1.2. Where relevant, the prescription, or a readily available local protocol, must also specify the following:

- brand name and formulation of the medicine;
- concentration or total quantity of medicine in the final infusion container or syringe;
- name and volume of diluent and/or infusion fluid;
- rate *and* duration of administration;
- stability information to determine the expiry date of the final product;
- the age and weight of any patient under 16 years of age, where relevant;
- arrangements for fluid balance or clinical monitoring should be made on an individual patient basis and according to local protocol and clinical need.

2: Preparation

2.1 General

2.1.1 Trust staff must not prepare substances for injection in advance of their immediate use or administer medication drawn into a syringe or container by another practitioner when not in their presence.

2.1.2 Read all prescription details carefully and confirm that they relate to the patient to be treated.

2.1.3 Calculate the volume of medicine solution needed to give the prescribed dose. Write the calculation down and obtain an independent check by another qualified healthcare professional.

2.1.4 Ensure that the area in which the medicine is to be prepared is as clean, uncluttered and free from interruption and distraction as possible. Preparation must take place in an area dedicated to this process e.g. clinical room.

2.1.5 Assemble all materials and equipment: sharps bin for waste disposal, medicine ampoule(s)/vial(s), diluent, syringe(s), safety needle(s), alcohol/disinfectant wipes, disposable protective gloves, clean re-usable plastic tray.

Check the following:

- expiry dates;
- damage to containers, vials or packaging;
- that medicines were stored as recommended, e.g. in the refrigerator.

2.1.6 Beware of the risk of confusion between similar looking medicine packs, names and strengths. Read all labels carefully.

2.1.7 Check that:

- the formulation, dose, diluent, infusion fluid and rate of administration correspond to the prescription and product information;
- the patient has no known allergy to the medicine;
- you understand the method of preparation.

2.1.8 Prepare the label for the prepared medicine (see 2.7 below).

2.1.9 Clean your hands according to local policy.

2.1.10 Put on a pair of disposable protective gloves.

2.1.11 Use a disinfectant wipe or spray (as recommended by current Infection Control Policy) to disinfect the surface of the plastic tray or use a disposable tray.

2.1.12 Assemble the required syringe(s) and safety needle(s). Peel open wrappers carefully and arrange all ampoules/vials, syringes and needles neatly in the tray.

2.1.13 Use a 'non-touch' technique, i.e. avoid touching areas where bacterial contamination may be introduced, e.g. syringe-tips, needles, vial tops. Never put down a syringe attached to an unsheathed needle.

2.1.14 Prepare the injection by following the manufacturer's product information or local guidelines, and the relevant guidance in 2.2 to 2.7 below.

2.2 Withdrawing solution from an ampoule (glass or plastic) into a syringe

2.2.1 Tap the ampoule gently to dislodge any medicine in the neck.

2.2.2 Snap open the neck of glass ampoules (away from the operator), using an ampoule snapper if required.

2.2.3 Attach a filter needle to a syringe (for glass ampoules) and draw the required volume of solution into the syringe. Plastic ampoules do not require a needle to be fitted to the syringe. Tilt the ampoule if necessary.

2.2.4 Invert the syringe and tap lightly to aggregate the air bubbles at the needle end. Expel the air carefully.

2.2.5 Remove the needle from the syringe and fit a new needle or insert the syringe into syringe packaging.

2.2.6 Label the syringe (see 2.7 below).

2.2.7 Keep the ampoule and any unused medicine until administration to the patient is complete to enable any further checking procedures to be undertaken.

2.2.8 If the ampoule contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.

2.2.9 The neck of some plastic ampoules is designed to connect directly to a syringe without use of a needle, after the top of the ampoule has been twisted off.

2.3 Withdrawing a solution or suspension from a vial into a syringe

2.3.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol/disinfectant wipe e.g. Sanicloth CHG 2%. Allow to dry for at least 30 seconds.

2.3.2 With the safety needle, draw into the syringe a volume of air equivalent to the required volume of solution to be drawn up.

2.3.3 Insert the safety needle into the vial through the rubber septum.

2.3.4 Invert the vial. Keep the needle in the solution and slowly depress the plunger to push air into the vial.

2.3.5 Release the plunger so that solution flows back into the syringe.

2.3.6 If a large volume of solution is to be withdrawn, use a push-pull technique. Repeatedly inject small volumes of air and draw up an equal volume of solution until the required total is reached. This ‘equilibrium method’ helps to minimise the build-up of pressure in the vial.

2.3.7 Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.

2.3.8 With the vial still attached, invert the syringe. With the needle and vial uppermost, tap the syringe lightly to aggregate the air bubbles at the needle end. Push the air back into the vial.

2.3.9 Fill the syringe with the required volume of solution then draw in a small volume of air. Withdraw the needle from the vial.

2.3.10 Expel excess air from the syringe. Remove the needle, dispose of in a sharps bin and insert the syringe into the syringe packaging.

2.3.11 The vial(s) and any unused medicine should be kept until administration to the patient is complete.

2.3.12 If the vial contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.

2.4 Reconstituting powder in a vial and drawing the resulting solution or suspension into a syringe

2.4.1 Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.

2.4.2 Use the procedure in 2.2 above to withdraw the required volume of diluent (e.g. water for injections or sodium chloride 0.9%) from ampoule(s) into the syringe.

2.4.3 Inject the diluent into the vial. Keeping the tip of the needle above the level of the solution in the vial, release the plunger. The syringe will fill with the air which has been displaced by the solution (if the contents of the vial were packed under a vacuum, solution will be drawn into the vial and no air will be displaced). If a large volume of diluent is to be added, use a push-pull technique (see 2.3.6).

2.4.4 With the syringe and safety needle still in place, gently swirl the vial(s) to dissolve all the powder, unless otherwise indicated by the product information. This may take several minutes.

2.4.5 Follow the relevant steps in 2.3 above to withdraw the required volume of solution from the vial into the syringe.

2.4.6 Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.

2.4.7 If a purpose-designed reconstitution device is used, the manufacturer's instructions should be read carefully and followed closely.

2.5 Adding a medicine to an infusion

2.5.1 Prepare the medicine in a syringe using one of the methods described in 2.2 to 2.4 above.

2.5.2 Check the outer wrapper of the infusion container is undamaged.

2.5.3 Remove the wrapper and check the infusion container itself in good light. It should be intact and free of cracks, punctures/leaks.

2.5.4 Check the infusion solution, which should be free of haziness, particles and discolouration.

2.5.5 Where necessary, remove the tamper-evident seal on the additive port according to the manufacturer's instructions or wipe the rubber septum on the infusion container with an alcohol/disinfectant wipe e.g. Sanicloth CHG 2% and allow to dry for at least 30 seconds.

2.5.6 If the volume of medicine solution to be added is more than 10% of the initial contents of the infusion container (more than 50ml to a 500ml or 100ml to a 1litre infusion), an equivalent volume must first be removed with a syringe and needle.

2.5.7 Inject the medicine into the infusion container through the centre of the injection port, taking care to keep the tip of the needle away from the side of the infusion container. Withdraw the needle and invert the container at least five times to ensure thorough mixing before starting the infusion.

2.5.8 Do not add anything to any infusion container other than a burette when it is hanging on the infusion stand since this makes adequate mixing impossible.

2.5.9 Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before administration is re-started, the contents of the burette must be carefully swirled to ensure complete mixing of the contents.

2.5.10 Check the appearance of the final infusion for absence of particles, cloudiness or discolouration. Discard or seek further guidance if unsure whether to proceed.

2.5.11 Label the infusion (see 2.7).

2.6 Diluting a medicine in a syringe for use in a pump or syringe-driver

2.6.1 Prepare the medicine in a syringe using one of the methods described above.

2.6.2 Draw the diluent into the syringe to be used for administration by the pump or syringe-driver. Draw in some air (slightly more than the volume of medicine needed) and remove the needle.

2.6.3 Stand the diluent syringe upright. Insert the safety needle of the syringe containing the medicine into the tip of the diluent (administration) syringe and add the medicine to it. Alternatively, a disposable sterile connector may be used to connect two syringes together directly.

2.6.4 Check the following:

- the total volume of injection solution in the syringe is as specified in the prescription and that the infusion can be delivered at the prescribed rate by the administration device chosen;
- the rate of administration is set correctly on the administration device and according to the manufacturer's instructions.

2.6.6 Fit a blind hub to the administration syringe and invert several times to mix the contents.

2.6.7 Remove the blind hub. Tap the syringe lightly to aggregate the air bubbles at the needle end. Expel the air and refit the blind hub.

2.6.8 Carefully check the syringe for cracks and leaks and then label it (see 2.7), especially noting the requirements specific to syringe drivers.

2.6.9 Check that the rate of administration is set correctly on the device before fitting the syringe, priming the administration set and starting the infusion device.

2.7 Labelling injection and infusion containers

2.7.1 All injections should be labelled immediately after preparation, or be readily identifiable, except for syringes intended for immediate push (bolus) administration by the person who prepared them. Under no circumstances should an operator be in possession of more than one unlabelled or readily identifiable syringe at any one time, nor must an unlabelled syringe be fitted to a syringe driver or similar device.

2.7.2 Labels used on injectable medicines prepared in clinical areas should not occlude the volume when attached, and should contain the following information:

- name of the medicine;
- strength;
- route of administration;
- diluent and final volume;
- patient's name;
- expiry date and time;
- name of the practitioner preparing the medicine.

2.7.3 Place the final syringe or infusion and the empty ampoule(s)/vials(s) in a clean plastic tray with the prescription for taking to the patient for administration.

3: Administration of an injectable medicine

3.1 Before administering any injection

3.1.1 Check all the following:

- patient's name, hospital/NHS Number or date of birth or address;
- prescriber's signature;
- the approved medicine name;
- the dose and frequency of administration;
- the date and route of administration;
- the allergy status of the patient.

3.1.2 Also check, where relevant:

- brand name and formulation of the medicine;
- concentration or total quantity of medicine in the final infusion container or syringe;
- name and volume of diluent and/or infusion fluid;
- rate *and* duration of administration;
- type of rate-control pump or device(s) to be used;
- the age and weight of any patient under 16 years of age, where relevant;
- date on which treatment should be reviewed.

3.1.3 Check that the medicine is due for administration at that time and has not already been given.

3.1.4 Assemble everything you need including any flushing solution(s) needed.

3.1.5 Wherever possible, two registrants should check medication to be administered intravenously prior to administration, one of whom should be the registrant who then administers the IV solution.

3.1.6 Explain and discuss the procedure with the patient.

3.1.7 Where intravenous infusion solutions are being administered, it is strongly recommended that these should be given via an appropriate infusion device, whenever possible.

3.1.8 Check any infusion already in progress. It should be free of haziness, particles and discolouration.

3.1.9 Check that an appropriate access device is in place. Flush it immediately before and after administration of a medicine, and between doses of different medicines administered consecutively. Also check the administration site for signs of leakage, infection or inflammation. If any of these are present, an appropriate practitioner must re-site the cannula.

3.1.10 All intravenous sites should be checked every time medicines are administered and status recorded on the 'Record of Insertion Devices' on a shift basis. This chart must also be used to record the insertion and removal of all intravenous devices ('VIP Chart').

3.2 Administration of injections – General

3.2.1 Check infusions. They should be should be free of haziness, particles and discolouration.

3.2.2 Use aseptic (non-touch) technique at all times.

3.2.3 Attach administration sets to infusion containers carefully, on a flat surface and using the technique appropriate to the type of container.

3.2.4 Prime the access device according to local policy immediately before starting an infusion.

3.2.5 Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before re-commencement, the contents of the burette must be carefully swirled to ensure complete mixing.

3.3 After administration

3.3.1 After completion of an intermittent infusion, flush the access device according to local policy.

3.3.2 Ask the patient to report promptly any soreness at the injection site or discomfort of any sort.

3.3.3 Make a detailed record of administration.

3.3.4 Dispose of equipment and sharps promptly and safely following appropriate Trust policy.

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Standard Operating Procedures for the Management of Controlled Drugs in Operating Theatres

Introduction

Separate Trust Standard Operating Procedures (SOPs) are in place for the management of controlled drugs in a) wards/departments, b) operating theatres and c) pharmacy departments. These SOPs cover prescribing, requisitioning, receipt, administration and returning of CDs to Pharmacy. The ward and theatres SOPs are available on Q-Pulse. Both SOPs should be read in conjunction with the policy statements laid out in Chapter 5 of the main Trust Medicines Policy and Procedure.

Please refer to Section 6 for additional guidance on the safe prescribing and administration of opioid medicines. These have been added in response to the NPSA Rapid Response Alert (July 08) – 'Reducing Dosing Errors with Opioid Medicines'

11. Prescribing of Controlled Drugs in Operating Theatres

1.1 Prescribing of controlled drugs will be in accordance with the Misuse of Drugs Act (1971) and its associated Regulations, and the Medicines Act (1968). Additional statutory measures for the management of CDs are laid down in the Health Act (2006) and its associated Regulations.

1.2 The Misuse of Drugs (Supply to Addicts) Regulations 1997 prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

1.3 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on in-patient prescription forms for in patient use. Medical doctors who have not achieved full registration with the GMC are <u>not</u> permitted to prescribe CDs for discharge prescriptions or for outpatients.

1.4 Non-medical prescribers are only permitted to prescribe those CDs that they are legally entitled to prescribe.

1.5 CDs must be prescribed on the in-patient prescription chart or the anaesthetics card. Where separate charts are used e.g. anaesthetic charts they should be cross-referenced on the main patients drug chart.

1.6 The written requirements for controlled drugs on these charts are the same as for other medicines:

- Drug name and form
- Route
- Dose
- Frequency (if prescribed “when required” e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24hrs)
- Include a finish time/date where appropriate
- Start date
- Signature of prescriber

The patient’s name, unit number and allergy status should also be written on the chart.

12. Requisitioning of Controlled Drugs for Operating Theatres

2.1 The registered nurse or midwife in charge of an operating theatre or theatre suite is responsible for the requisitioning of CDs for use in that area. Even if the ward or department is managed by someone other than a nurse, the most senior registered nurse or midwife present is responsible for controlled drugs under the present Regulations.

2.2 The registered nurse or midwife in charge can delegate the task of preparing a requisition to another, such as a registered nurse or registered operating department practitioner (ODP). However, legal responsibility remains with the registered nurse or midwife in charge.

2.3 Orders for CDs must be made in the approved Trust Controlled Drugs Order Book using a separate page for each item and signed (plus printed name) by an authorised signatory. Order books should be kept in a safe place in the theatre to avoid misappropriation of controlled drugs.

2.4 An up to date list of authorised signatories for the ordering of controlled drugs must be kept in the theatre and in the Pharmacy Departments. It

will be the responsibility of the theatre manager to maintain each list and only staff on the list will be able to order controlled drugs.

2.5 Requisitions must contain the following:

- Name of hospital
- Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature and printed name of registered nurse
- Date

2.6 Ideally, orders for CDs should reach the pharmacy by 11am each weekday morning for delivery in the afternoon. Completed order books must be delivered by hand to pharmacy staff i.e. **not** sent through the internal mail. Orders on a Saturday must be for urgent items only.

13. Receipt of Controlled Drugs in Operating Theatres

3.1 CDs will normally be delivered to the theatre by a member of staff authorised by the Pharmacy Department who will sign the top copy which will be retained by the Pharmacy.

3.2 If CDs are needed urgently between delivery rounds a responsible representative from the ward, nominated by the theatre manager, may collect them directly from the pharmacy. Staff collecting CDs from the Pharmacy must display valid ID.

3.3 In each case, the registered health care practitioner who receives the controlled drugs must check the CDs against the requisition – including the number ordered and received. Any tamper-evident seals on packs should be left intact when they are received from pharmacy, this will simplify and speed up routine checks.

3.6 If a discrepancy exists between the order and the CDs delivered/collected, the Pharmacy Department must be contacted **immediately**.

3.5 If the order is correct, the order book must be signed in the presence of the messenger. The order book will then stay on the theatre.

3.6 Theatres are required to use special 'Theatre Controlled Drug Record Books' (and not 'Ward Controlled Drug Record Books') to record receipts and issues of controlled drugs. These are available from the Pharmacy Departments.

3.7 As soon as possible, after receipt of the CDs from the pharmacy, details of stock delivered/collected must be entered into the appropriate sections of the Theatre CD Record Book.

There should be a separate Theatre CD record book for each theatre.

The details to be entered into the appropriate page on the register are:

- Date
- Quantity received

- Serial number of requisition
- Signature of person making the entry
- New stock balance

3.8 It is advisable at this stage to check the new balance tallies with the quantity that physically exists in the theatre.

3.10 The received CDs should be placed in the CD cupboard.

3.10 As a general rule it is good practice that the receiving person should not be the same person who ordered the CDs. It is also good practice that receipt of CDs and updating of the Theatre CD Record Book is witnessed by a second competent professional wherever possible.

14. Administration of Controlled Drugs in Operating Theatres

4.1 The administration of CDs should comply with all local policies and procedures for the administration of medicines (see Chapter 4 of The Trust Medicines Policy). Nurses and midwives must follow Nursing and Midwifery standards and guidance.

4.2 The administration of controlled drugs must be double checked by a second practitioner throughout the whole of the administration process and this checker must act as a second signatory in all documentation.

4.3 Where two practitioners are involved in the administration of CDs, one of them must be a registered practitioner i.e. nurse, midwife, doctor or ODP. Both practitioners should be present during the whole of the administration procedure.

4.4 In line with the administration of all medicines the following procedure should be followed when administering CDs :

q) Read the prescription chart carefully. If there is any doubt about the legibility of the prescription or other particulars such as dosage, route, time or frequency of the administration of the medicine, the nurse or midwife should check with the prescriber concerned or the pharmacist.
r) Check that the prescribed dose has not already been administered.
s) Select the medicine required and check the following: -
   - the medicine (name, strength and formulation) with the prescription
   - the calculation, if any
   - the measured dose
   - the correct time
   - the correct route
   - appropriate storage;
   - the expiry date;
   - the validity of the prescription
   - any known allergies.
t) Take the measured dose and prescription chart to the patient.
u) Positively identify the in-patient using the patient name-band, and other patients by asking the patient to state his/her name and date-of-birth.
v) Administer the medication to the patient.

w) In the case of oral medication, ensure the medicine has been swallowed.
x) Sign for the administration or enter the details of non-administration in the appropriate place on the prescription chart.

4.5 For CDs administered, the following details should be recorded in the appropriate page of the Theatre CD Record Book, and countersigned by the checker:

- Date and time when dose administered
- Name of patient
- Quantity administered
- Name/Signature of person who administered the dose
- Name/Signature of witness (where there is one)
- Balance left in stock after administration

4.6 Substances prepared for administration and subsequently not used must be disposed of in an appropriate manner (see 4.8) in the presence of a second person who may be a pharmacist, nurse or doctor. They must not be returned to the containers from which they were removed; the details must be entered in the appropriate section of the Theatre CD Record Book.

4.7 The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the Theatre CD Record Book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006. www.aagbi.org*] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed.

4.8 If part of a vial is administered to a patient, the registered nurse, midwife or registered health professional should record the amount supplied, the amount administered and the amount destroyed in the appropriate column of the Theatre CD Record Book, e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*5mg supplied, 2.5mg administered*, *2.5mg destroyed*". This should be witnessed by a second registered nurse midwife or registered health professional who should also sign the record. If a second registered nurse midwife or registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant. The unused/wasted portion of the dose should be disposed of as in 4.9.

4.9 Small amounts of CDs can be destroyed and rendered irretrievable by emptying into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

4.10 Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.

4.11 A separate policy exists within theatres for the management of all aspects of patient controlled analgesia.

15. Returning Controlled Drugs to Pharmacy

5.1 Unused CD stock or stock no longer required in theatres should be returned to the pharmacy. Such CD stock can be re-issued by the pharmacy provided it was initially issued by that pharmacy and has at all times been under the control of that hospital. The pharmacy department will carry out a risk assessment of CDs returned to pharmacy to ensure they are fit for re-use.

5.2 CDs that are time-expired or otherwise unfit for use should also be returned to the pharmacy for safe destruction and onward disposal. Any other controlled drug that is no longer needed in theatres should be returned to pharmacy. This should be done as soon as is practicable.

5.3 In the event of a theatre wishing to return CDs to the Pharmacy for any of the above reasons, the local Pharmacy Department should be contacted either by telephone. A pharmacist will then attend the theatre and assist and witness the return transaction. Alternatively, a member of theatre staff nominated by the theatre manager may bring stock for return to the Pharmacy along with the Theatre CD Record Book to the Pharmacy in order to record the details.

5.4 Details of CDs returned to Pharmacy must be recorded in the Theatre CD record book. An entry should be made in the appropriate page showing:

- Date CD Returned
- Reason for Return
- Quantity Returned
- Name/Signature of Responsible Person on the Ward
- Name/Signature of witness (usually pharmacist)
- Balance left in stock after removal of returned CDs

5.5 The pharmacist will then arrange for the CDs to be transferred to the Pharmacy in a safe and secure way.

6. Safe Prescribing and Administration of Opioid Medicines

6.5 Many incidents are reported to the National Reporting and Learning System (NRLS) concerning patients receiving unsafe doses of opioid medicines, where a dose or formulation was incorrect, based on the patient's previous opioid dose.

6.6 Every member of the team has a responsibility to check that the intended dose is safe for the individual patient. Knowledge of previous opioid dose is essential for the safe use of these products. There is a wide variety of opioid medicines, and supply shortages may result in products being used which are unfamiliar to practitioners.

6.3 When opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, the healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not **normally** more than 50% higher than the previous dose).
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

6.4 While dose increments should be in line with this guidance, it is recognised that in palliative care higher than normal doses may be required. These recommendations are not designed to restrict clinical use of opioid medicines, but to ensure they are used in a way that is as safe as possible for patients**.**

6.8 Usual starting doses for opioid medicines may vary depending on the type of patient e.g. doses in paediatric patients are likely to be very different to those in adult patients. Information relating to starting doses, dose conversion and formulations may be found in the following texts (other texts may also be relevant):

- British National Formulary (Individual product monographs and 'Prescribing in Palliative Care' section)
- British National Formulary for Children
- Palliative Care Formulary or www.palliativedrugs.com
- Summary of Product Characteristics (SPC) of individual products

6.6 The NPSA have produced a set of algorithms which may be helpful for staff in reducing risks of dosing errors with opioid medicines. These are available at:

http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/reducing-dosing-errors-with-opioid-medicines/

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Standard Operating Procedures for the Management of Controlled Drugs in Wards and Departments

Introduction

Separate Trust Standard Operating Procedures (SOPs) are in place for the management of controlled drugs in a) wards/departments, b) operating theatres and c) pharmacy departments. These SOPs cover prescribing, requisitioning, receipt, administration and returning of CDs to Pharmacy. The ward and theatres SOPs are available on Q-Pulse. Both SOPs should be read in conjunction with the policy statements laid out in Chapter 5 of the main Trust Medicines Policy and Procedure.

Please refer to Section 6 for additional guidance on the safe prescribing and administration of opioid medicines. These have been added in response to the NPSA Rapid Response Alert – 'Reducing Dosing Errors with Opioid Medicines'

16. Prescribing of Controlled Drugs

1.1 General Principles

1.1.1 Prescribing of controlled drugs will be in accordance with the Misuse of Drugs Act (1971) and its associated Regulations, and the Medicines Act (1968). Additional statutory measures for the management of CDs are laid down in the Health Act (2006) and its associated Regulations.

1.1.2 The Misuse of Drugs (Supply to Addicts) Regulations 1997 prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

1.1.4 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on in-patient prescription forms for in patient use. Medical doctors who have

not achieved full registration with the GMC are not permitted to prescribe CDs for discharge prescriptions or for outpatients.

1.1.4 Non-medical prescribers are only permitted to prescribe those CDs that they are legally entitled to prescribe.

1.2 Prescribing for In-patients

1.2.1 For hospital inpatients, CDs must be prescribed on the in-patient prescription chart or the anaesthetics card.

1.2.2 The written requirements for controlled drugs on these charts are the same as for other medicines:

- Drug name and form
- Route
- Dose
- Frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24hrs)
- Include a finish date where appropriate
- Start date
- Signature of prescriber

The patient's name, unit number and allergy status should also be written on the chart.

1.3 Prescribing for Discharge Patients

1.3.2 Prescriptions for CDs for patients who are going home (discharge medicines) should be added to the patient's Electronic Discharge Prescription (EDN) along with any other medication. Beside the CD entry on the EDN a red icon will appear which directs the prescriber to a separate 'Controlled Drug Discharge Prescription' sheet with the patient details already filled in. This must be printed out and the area that requires handwritten details (e.g. dosage form, strength, instructions and total quantity to be dispensed in words and figures) completed by the prescriber. The prescriber must also sign and date this prescription.

This completed sheet will be required by the Pharmacy dept. to allow them to legally dispense the CDs on the EDN.

1.4 Prescribing for Out-Patients

1.4.1 Prescriptions for CDs for out-patients can either be written on hospital out-patient prescription forms or a hospital FP10 prescription for a community pharmacy to dispense.

These prescriptions must conform to all handwriting requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 1.5).

1.5 Handwriting Requirements for Controlled Drugs (Out-Patients/Discharge)

1.5.1 A prescription for Schedule 2 and 3 CDs (with the exception of temazepam and midazolam preparations) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated:

- The patient's full name, address and, where appropriate, age
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures

1.5.2 The prescription must be signed by the prescriber with his/her usual signature, in his own handwriting (this must be handwritten) and dated by him/her (the date does not have to be handwritten).

17. Requisitioning of Controlled Drugs for Wards and Departments

2.1 The registered nurse or midwife in charge of a ward or department is responsible for the requisitioning of CDs for use in that area. Even if the ward or department is managed by someone other than a nurse, the most senior registered nurse or midwife present is responsible for controlled drugs under the present Regulations.

2.2 The registered nurse or midwife in charge can delegate the task of preparing a requisition to another, such as a registered nurse. However, legal responsibility remains with the registered nurse or midwife in charge.

2.3 Orders for CDs must be made in the approved Trust Controlled Drugs Order Book using a separate page for each item and signed (plus printed name) by an authorised signatory. Order books should be kept in a safe place on the ward to avoid misappropriation of controlled drugs.

2.4 An up to date list of authorised signatories for the ordering of controlled drugs must be kept on the ward/department and in the Pharmacy Departments. It will be the responsibility of the ward/ department

manager to maintain each list and only staff on the list will be able to order controlled drugs.

2.5 Requisitions must contain the following:

- Name of hospital
- Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature and printed name of registered nurse
- Date

2.6 Ideally, orders for CDs should reach the pharmacy by 11am each weekday morning for delivery in the afternoon. Completed order books must be delivered by hand to pharmacy staff i.e. **not** sent through the internal mail. Orders on a Saturday must be for urgent items only.

18. Receipt of Controlled Drugs in Wards and Departments

3.1 CDs will normally be delivered to the ward/department by a member of staff authorised by the Pharmacy Department who will sign the top copy which will be retained by the Pharmacy.

3.2 If CDs are needed urgently between delivery rounds a responsible representative from the ward, nominated by the ward manager, may collect them directly from the pharmacy. Staff collecting CDs from the Pharmacy must display valid ID.

3.3 In each case, the registered health care practitioner who receives the controlled drugs must check the CDs against the requisition – including the number ordered and received. Any tamper-evident seals on packs should be left intact when they are received from pharmacy, this will simplify and speed up routine checks.

3.7 If a discrepancy exists between the order and the CDs delivered/collected, the Pharmacy Department must be contacted <u>immediately.</u>

3.5 If the order is correct, the order book must be signed in the presence of the messenger. The order book will then stay on the ward.

3.6 As soon as possible, after receipt of the CDs from the pharmacy, details of stock delivered/collected must be entered into the appropriate sections of the CD Record Book.

The details to be entered into the appropriate page on the register are:

- Date
- Quantity received
- Serial number of requisition
- Signature of person making the entry
- New stock balance

3.7 It is advisable at this stage to check the new balance tallies with the quantity that physically exists on the ward.

3.10 The received CDs should be placed in the CD cupboard.

3.11 As a general rule it is good practice that the receiving person should not be the same person who ordered the CDs. It is also good practice that receipt of CDs and updating of the CD Record Book is witnessed by a second competent professional wherever possible.

19. Administration of Controlled Drugs

4.1 The administration of CDs should comply with all local policies and procedures for the administration of medicines (see Chapter 4 of The Trust Medicines Policy). Nurses and midwives must follow Nursing and Midwifery standards and guidance.

4.2 The administration of controlled drugs must be double checked by a second practitioner throughout the whole of the administration process and this checker must act as a second signatory in all documentation.

4.3 Where two practitioners are involved in the administration of CDs, one of them must be a registered practitioner i.e. nurse, midwife or doctor. Both practitioners should be present during the whole of the administration procedure.

4.4 In line with the administration of all medicines the following procedure should be followed when administering CDs :

y) Read the prescription chart carefully. If there is any doubt about the legibility of the prescription or other particulars such as dosage, route, time or frequency of the administration of the medicine, the nurse or midwife should check with the prescriber concerned or the pharmacist.

z) Check that the prescribed dose has not already been administered.

aa) Select the medicine required and check the following: -

- the medicine (name, strength and formulation) with the prescription
- the calculation, if any
- the measured dose
- the correct time
- the correct route
- appropriate storage;
- the expiry date;
- the validity of the prescription
- any known allergies.

bb) Take the measured dose and prescription chart to the patient.

cc) Positively identify the in-patient using the patient name-band, and other patients by asking the patient to state his/her name and date-of-birth.

dd) Administer the medication to the patient.

ee) In the case of oral medication, ensure the medicine has been swallowed.

ff) Sign for the administration or enter the details of non-administration in the appropriate place on the prescription chart.

4.5 A record must be made in the ward or department CD Record Book when a CD is removed from the CD cupboard for the purposes of administration and countersigned by the checker.

4.6 For CDs administered, the following details must be recorded in the appropriate page of the CD Record Book :

- Date and time when dose administered
- Name of patient
- Quantity administered
- Name/Signature of person who administered the dose
- Name/Signature of witness (where there is one)
- Balance left in stock after administration

4.7 Substances prepared for administration and subsequently not used must be disposed of in an appropriate manner (see 4.8) in the presence of a second person who may be a pharmacist, nurse or doctor. They must not be returned to the containers from which they were removed; the details must be entered in the appropriate section of the CD Record Book.

4.8 If part of a vial is administered to the patient, the registered nurse, midwife or registered health professional should record the amount given and the amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* ". This should be witnessed by a second registered nurse midwife or registered health professional who should also sign the record. If a second registered nurse midwife or registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant. The unused/wasted portion of the dose should be disposed of as in 4.9

4.9 Small amounts of CDs can be destroyed and rendered irretrievable by emptying into a sharps bin. The emptied vial or ampoule should then also be placed in the sharps bin. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

20. Returning Controlled Drugs to Pharmacy

5.1 Unused CD stock or stock no longer required in wards or departments may be returned to the pharmacy. Such CD stock can be re-issued by the pharmacy provided it was initially issued by that pharmacy and has at all times been under the control of that hospital. The pharmacy department will carry out a risk assessment of CDs returned to pharmacy to ensure they are fit for re-use.

5.2 CDs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal. Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable.

5.3 In the event of the ward or department wishing to return CDs to the Pharmacy for any of the above reasons, the local Pharmacy Department should be contacted either by telephone or via any of the Pharmacy ward staff. A pharmacist will then attend the ward and assist and witness the return transaction. Alternatively, a member of the ward staff nominated by the ward manager may bring stock for return to the Pharmacy along with the CD Record Book to the Pharmacy in order to record the details.

5.4 Details of CDs returned to Pharmacy must be recorded in the ward CD record book. An entry should be made in the appropriate page showing:

- Date CD returned
- Reason for return
- Quantity returned
- Name / signature of responsible person on the ward
- Name / signature of witness (usually pharmacist)
- Balance left in stock after removal of returned CDs

5.5 The pharmacist will then arrange for the CDs to be transferred to the Pharmacy in a safe and secure way.

6. Safe Prescribing and Administration of Opioid Medicines

6.7 Many incidents are reported to the National Reporting and Learning System (NRLS) concerning patients receiving unsafe doses of opioid medicines, where a dose or formulation was incorrect, based on the patient's previous opioid dose.

6.8 Every member of the team has a responsibility to check that the intended dose is safe for the individual patient. Knowledge of previous opioid dose is essential for the safe use of these products. There is a wide variety of opioid medicines, and supply shortages may result in products being used which are unfamiliar to practitioners.

6.3 When opioid medicines are prescribed, dispensed or administered, in anything other than acute emergencies, the healthcare practitioner concerned, or their clinical supervisor, should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient or their representative (although not in the case of treatment for addiction), the prescriber or through medication records.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not **normally** more than 50% higher than the previous dose).
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

6.9 While dose increments should be in line with this guidance, it is recognised that in palliative care higher than normal doses may be required. These recommendations are not designed to restrict clinical use of opioid medicines, but to ensure they are used in a way that is as safe as possible for patients.

6.10 Usual starting doses for opioid medicines may vary depending on the type of patient e.g. doses in paediatric patients are likely to be very different to those in adult patients. Information relating to starting doses, dose conversion and formulations may be found in the following texts (other texts may also be relevant):

- British National Formulary (Individual product monographs and 'Prescribing in Palliative Care' section)
- British National Formulary for Children
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- Summary of Product Characteristics (SPC) of individual products

6.6 The NPSA have produced a set of algorithms which may be helpful for staff in reducing risks of dosing errors with opioid medicines. These are available at : http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/reducing-dosing-errors-with-opioid-medicines/

Version 1

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Version 2

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Version 3

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Version 4

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